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General Comment (Automatic Updates)	Commenter states under the proposed regulations, future revisions of the applicable guidelines by ACOEM or the Work Loss Data Institute will not become part of the MTUS unless the DWC amends the regulations. Commenter opines in future years this may become confusing for physicians trying to determine which guidelines are applicable. Commenter suggests the guidelines adopted by those respective organizations as of the date of the request for treatment be applicable for review purposes, unless the DWC has taken subsequent action to deny the use of a revision. Commenter requests if the DWC declines to take this step, DWC should take whatever steps are necessary to make all current guidelines available on its website. Commenter states this would at least help to make sure physicians can locate the relevant and applicable guidelines.	Harry J. Monroe, Director of Government Relations Coventry Health Care August 12, 2008	**Disagree.** DWC is precluded from automatically adopting future updates of documents incorporated into a rulemaking without formal rulemaking. If future updates are automatically incorporated by reference into the MTUS regulations, which have the full force and effect of law, then the Administrative Director has delegated the power to make regulatory law in California to a private association with no limitation whatsoever and with no rational basis for determining what policy will be implemented. (1 CCR §20, Kugler v. Yocum, 69 Cal. 2nd 371, 375-377 (Cal. 1968).) On the other hand, with medical advances likely to occur and become current practice, it will be necessary for the DWC to update the MTUS on a regular basis. This update will be accomplished through formal rulemaking. The applicability of the MTUS becomes effective when the regulations are approved through the formal rulemaking process. After the regulations become effective, the MTUS is applicable as presumptively correct until it is updated again through formal rulemaking. If there are changes in the medical evidence as a result of medical advances before the next update, then Section 9792.25 allows both physicians and claims	None.

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			administrators to attempt to overcome the presumption with new medical evidence to support the new treatment approach over the version of the MTUS in effect at the time of the dispute.	
General Comment (Updates)	Commenter inquires as to how the guidelines will be updated to reflect advances in medical or surgical treatment, given that there are frequent changes in knowledge and in consensus of various medical specialties. If this is not taken into account, then contents of these guidelines will gradually lose their applicability.	Eduardo Aenlle, MD. July 23, 2008	**Disagree.** See response above.	None.
General Comment	Commenter speaks of the difficulties he encountered after the original Medical Treatment Utilization Schedule regulations were adopted. He experienced delays and denials for needed treatment and alleges that other injured workers have experienced similar adversity.	James Kyle Injured Worker Oral Testimony August 12, 2008	**Disagree.** The comment does not substantively address the proposed changes to the current medical treatment utilization schedule regulations.	None.
General Comment	Commenter details the many problems that her husband has encountered trying to get treatment for his workers' compensation injury specific due to utilization review.	Nancy Chance Wife of Injured Worker, Richard Chance August 12, 2008 Written Comment	**Disagree.** The comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
General Comment (Appendixes)	Commenter states a number of important documents have been given as appendixes to the Initial Statement of Reasons. Commenter believes these appendices should instead be incorporated into the regulations. Commenter states that these include Appendices B, C, D, and E.	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Agree in part. Agree** that Appendixes C, D, and E should be incorporated into the MTUS. Accordingly, Appendix D—Chronic Pain Medical Treatment Guidelines, Division of Workers' Compensation and Official Disability Guidelines References is incorporated into the MTUS in proposed section 9792.24.2(f), Appendix C—Postsurgical Treatment Guidelines, Evidence-Based Reviews is incorporated into	The following sections have been added to the proposed regulations: **Section 9792.24.2** (e) Appendix D—Chronic Pain Medical Treatment Guidelines Division of Workers' Compensation and Official Disability Guidelines References—is incorporated by reference

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			the MTUS in proposed section 9792.24.3(d)(2), and Appendix E—Postsurgical Treatment Guidelines Work Loss Data Institute-Official Disability Guidelines References is incorporated into the MTUS in proposed section 9792.24.3(d)(3). **Disagree** that Appendix B—Chronic Pain Medical Treatment Guidelines Evidence-Based Reviews be incorporated into the MTUS because it is not necessary at this point. After the Notice of Proposed Rulemaking issued in June of 2007 and during the 45-day comment period, the editors of the Work Loss Data Institute revised the ODG guidelines and performed their own evidence-based reviews (EBRs). Those EBRs included DWC's EBRs. Accordingly, it is not necessary to have DWC's EBRs in Appendix B incorporated into the regulations as they have been absorbed by ODG's EBRs, and are included in their guidelines and are part of the Chronic Pain Medical Treatment Guidelines, Part 2.	into the MTUS as supplemental part of the Chronic Pain Medical Treament Guidelines. A copy of Appendix D may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov. **Section 9792.24.3(d)(2) and Section 9792.24.3(d)(3):** (2) Appendix C—Postsurgical Treatment Guidelines Evidence-Based Reviews—is incorporated by reference into the MTUS as supplemental part of the Postsurgical Treatment Guidelines. A copy of Appendix C may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov. (3) Appendix E—Postsurgical Treatment Guidelines Work Loss Data Institute-Official Disability Guidelines References—is

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				incorporated by reference into the MTUS as supplemental part of the Postsurgical Treatment Guidelines. A copy of Appendix E may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov.
General Comment (Appendixes)	Commenter states that ACOEM's chronic pain guidelines include strength of evidence rating for each recommendation. Commenter states that CWCI believes it is important to list the strength of evidence rating for each treatment guideline so that it can be used by treating physicians, reviewers, adjudicants, and judges to determine whether the presumption of correctness for a treatment addressed in the Chronic Pain section of the MTUS is overcome by superior evidence. That listing will reduce the number of disputes and the resources needed to resolve such issues. Commenter also states that including the appendix of evidence based reviews in the regulations by reference and specifying MTUS rating criteria for each study in the appendix will also reduce the number of disputes and related resources.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree.** See response to comments submitted by Steven Suchil, Assistant Vice President, American Insurance Association, August 12, 2008, above.	See action in connection with comment submitted by by Steven Suchil, Assistant Vice President, American Insurance Association, August 12, 2008, above.
General Comment (Unrelated)	Commenter states it was recently brought to her attention there have been some misconceptions as to whether the journal of the International Neuromodulation Society, *Neuromodulation: Technology at the Neural Interface*, is peer-reviewed. Commenter states she is writing to confirm that their journal has been peer-reviewed since its inception in 1998, and that it continues to be peer-reviewed to this day! Commenter states that every article that is	Tia Sofatzis, Managing Editor Neuromodulation: Technology at the Neural Interface July 21, 2008	**Disagree.** Comment does not address the substance of the proposed regulations.	None.

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	published in *Neuromodulation* is systematically reviewed by three reviewers from their Editorial Board (or by other experts in the field) in their web-based manuscript submission, review and tracking program, Manuscript Central. Commenter states that more information is available on their journal's home page and provides their web page information.			
9792.20(c) Chronic Pain Definition	Commenter states the most commonly accepted meaning of chronic pain, including in the medical literature and medical research, is pain that endures more than 3 months. Commenter further states since the MTUS is based on medical evidence, she believes this is the most logical, appropriate and useful way to define chronic pain. Commenter adds ACOEM also defines chronic pain this way. Commenter indicates the International Association for the Study of Pain has defined chronic pain as "pain that persists beyond normal tissue healing time, which is assumed to be 3 months" *(International Association for the Study of Pain. Classification of chronic pain. Pain 1986; Suppl **3:** S1–S226)*. Commenter suggests the DWC may wish to consider this definition as a possible alternative. Commenter observes the ODG Chronic Pain Guidelines refer to several different definitions for chronic pain: by multiple durations (generally from 6 weeks to 3 months after the onset of symptoms) and by pain that persists for at least 30 days beyond the usual course of an illness. Commenter states the proposed definition is not numbered among these definitions. Commenter states it therefore appears the treatment recommended in the proposed guidelines was not fashioned for this definition of chronic pain. Commenter states defining chronic pain as "any pain that persists beyond the anticipated time of tissue	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree in part. Agree** that the definition of the term "chronic pain" merits a revision. The term "chronic pain" is defined in the proposed regulations as "any pain that persists beyond the anticipated time of tissue healing." In the Initial Statement of Reasons (ISOR), we indicated that the definition was crafted based on *Bonica's Management of Pain*, wherein the term is defined, in pertinent part, as "pain that extends beyond the expected period of healing." (Turk, D. and Okifuji A. *Pain Terms and Taxonomies* in Bonica's Management of Pain, 3rd edition. Philadelphia, PA, Lippincott Williams and Wilkins:17.) In reviewing the definition of chronic pain in light of the comments submitted by the public, it is noted that DWC's definition does not accurately describe the definition as presented by Bonica's text book. Thus, the definition is corrected to reflect the definition as quoted in the textbook and in the ISOR to state chronic pain means "pain that extends beyond the expected period of	Section 9792.20(c) is amended as follows: (c) "Chronic pain" means any pain that persists beyond the anticipated time of ~~tissue~~ healing.

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	healing" raises a number of issues. Who or what will define "anticipated time of tissue healing?" Is there a standard reference for the anticipated time based on an average of many events or on a standard deviation from the average? Or is it based on the physician's experience? Commenter sets forth the example that if a physician anticipates tissue healing within 7 days for a cut or sprain, and an injured employee still reports pain on the 8th day, under this definition the employee is suffering chronic pain and, according to Section 1, page 6, "should be directed toward resources capable of addressing medical and psychosocial barriers to recovery." Commenter indicates the definition may be over-inclusive and potentially result in unnecessary referrals to chronic pain programs and specialists. Commenter adds on the other hand, those who suffer pain from chronic conditions for which tissue healing is not expected or expected in the distant future, would not be characterized as having chronic pain under this definition, and may not receive appropriate referrals. Commenter submits two alternative recommendations for the definition of "chronic pain as contained in section 9792.20(c): (c) "Chronic pain" means any pain ~~that persists beyond the anticipated time of tissue healing~~ of more than 3 months duration. (c) "Chronic pain" means any pain that persists beyond the anticipated time of tissue healing, which is assumed to be more than 3 months duration.		healing." **Disagree** with the comment that the most commonly accepted meaning of chronic pain, including ACOEM's definition of chronic pain, is pain that endures more than 3 months. ACOEM indicates that "[t]he distinction between acute and chronic pain is somewhat arbitrary. Chronicity may be reached from one to six months post-injury. The International Association for the Study of Pain has stated three months is the definitional time frame, while the American Psychiatric Association uses a six-month limit. The most clinically useful definition might be that 'chronic pain persists beyond the usual course of healing of an acute disease or beyond a reasonable time for an injury to heal.' " (ACOEM Practice Guidelines, at p. 108.) It is noted that in its Chronic Pain Update, ACOEM reiterates the same definition for chronic pain as "chronic pain persists beyond the usual course of healing of an acute disease or beyond a reasonable time for an injury to heal," at p. 29, and acknowledges that for some conditions a "course of healing" is not an appropriate referent, citing examples of various arthritic conditions, spinal stenosis, or certain persistent neurological	

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			conditions, which are more appropriately labeled chronic pain. (ACOEM. *Occupational Medicine Practice Guidelines*, 2nd Edition, *Chronic Pain* (Revised 2008), American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org.), at p. 29.) With regard to commenter's observation that the ODG Chronic Pain Guidelines refer to several different definitions for chronic pain (see Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers' Comp-Chapter on Pain (Chronic), version dated October 23, 2008, at p. 2), DWC acknowledges that ODG does use various definitions. It is noted that these definitions are similar to the various definitions contained in the ACOEM Practice Guidelines. Most importantly, however, DWC is not adopting ODG's introduction. The definition as adopted by DWC has been discussed above, the treatment guidelines as adapted into the MTUS are appropriate for the diagnosis of chronic pain regardless of when the diagnosis is made. Commenter further references DWC's definition of chronic pain	

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			and questions its application. With regard to Commenter's example of a sprain, DWC notes that, applying its definition, if a sprain is slower to heal than expected, but it nevertheless is still getting better, the clinician generally will recognize that there is variability in the healing response for that specific patient and will not diagnose chronic pain in these circumstances because the patient is anticipated to get better. Moreover, DWC has revised its definition and has removed the word "tissue" to match the definition in Bonica's text. By stating that chronicity is beyond healing will accommodate diagnoses where healing is not expected to occur.	
9792.20(c) Chronic Pain Definition	Commenter states the definition of "chronic pain" lacks clarity and will create disputes and increased litigation. Commenter states the phrase "anticipated time of tissue healing" will almost certainly be interpreted in various ways by various examiners. Commenter states that a definition must be tied to a specific guideline or individual, such as the Primary Treating Physician, in order to achieve clarity. Commenter indicates the lack of a clear and precise definition will present another issue for dispute, along with resulting wasted time, money, and energy. Commenter recommends the definition follow the dictates of Section 9792.24.2 (b) and Part I of the Chronic Pain Guideline by stating, "The chronic pain medical treatment guidelines apply when the patient has chronic pain as determined by following the	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Agree in part. Agree** for the reasons set forth in the response to Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, set forth above. Further, DWC agrees that an explanation of the framework to manage all chronic pain conditions, even when the injury is not addressed in the clinical topics section of the MTUS could be clarified. Accordingly, the first paragraph of the Introduction of the Chronic Pain Medical Treatment Guidelines at page 1 is	The first paragraph of the Introduction of the Chronic Pain Medical Treatment Guidelines, at page 1, is modified as follows: "The chronic pain medical treatment guidelines apply when the patient has chronic pain as determined by following the clinical topics section of the Medical Treatment Utilization Schedule (MTUS). In following the clinical topics section, the physician begins

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	clinical topics." Commenter states that if such a clarification is provided here it should also be placed in Section 9792.24.1 (a) (3) and in Part 1 of the Chronic Pain Guideline.		amended for clarification purposes as reflected in the next column. **Disagree** with the comment that the definition of "chronic pain" lacks clarity and will create disputes and increased litigation. In providing a definition for this term DWC's intention is define a key concept that works within a framework to manage all chronic pain conditions, even when the injury is not addressed in the clinical topics section of the MTUS. Contrary to commenter's assertions, the present absence of chronic pain medical treatment guidelines, results in increased utilization review, decreased access, increased litigation, and delays. By adopting chronic pain medical treatment guidelines, with a clear definition of what constitutes chronic pain, this serves to facilitate evidence-based medical care for injured workers for the continuum of care from acute to chronic pain management. **Disagree** with commenter's suggestion for a revised definition of chronic pain as set forth in his comment. Commenter does not offer a definition for the term "chronic pain." Commenter merely offers an alternative application of chronic pain as a definition, e.g., "[t]he chronic pain medical	with an assessment of the presenting complaint and a determination as to whether there is a 'red flag for a potentially serious condition' which would trigger an immediate intervention. Upon ruling out a potentially serious condition, conservative management is provided ~~and the patient is reassessed over the next 3-4 weeks~~. If the complaint persists ~~during this interval~~, the physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary. ~~The chronic pain medical treatment guidelines apply to~~ If the patient~~s~~ continues to have pain that persists beyond the anticipated time of healing, ~~who fail to recover and continue to have persistent complaints~~ without plans for definitive treatment, such as surgical options, the chronic pain medical treatment guidelines apply. This provides a framework to manage all chronic pain conditions, even when the injury is not addressed in the clinical topics section of the MTUS."

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			treatment guidelines apply when the patient has chronic pain as determined by following the clinical topics." As stated above, in providing a definition for this term DWC's intention is to define a key concept that works within a framework to manage all chronic pain conditions, even when the injury is not addressed in the clinical topics section of the MTUS. Moreover, Commenter's suggestion that the definition of chronic pain must be tied to an individual such as the primary treating physician is an incorrect application of the guidelines because the chronic pain guidelines is a model intended to apply to physicians, patients, families, healthcare providers, carriers, and compensation systems.	
9792.20(c) Chronic Pain Definition	Commenter states the definition of "chronic pain" includes pain that may not be chronic. Commenter believes that under the current definition, anyone complaining of pain from a minor cut after 5 days or a week would be viewed as suffering from chronic pain. Commenter opines that this definition alone is likely to breed disputes.	Keith Bateman, Vice President Property Casualty Insurers Association of America August 12, 2008	**Disagree.** See response to Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, above.	None.
9792.20(e) Evidence-based concept	Commenter states as DWC goes forward with its efforts to improve the MTUS and care for injured workers, DWC should consider several principles that he believes are essential: The first principle is that any guidelines adopted should be truly evidence-based. Commenter states practice guidelines are only as good as the methods used to develop them - and ACOEM is	Steven C. Schumann, M.D., Legislative Chair Western Occupational & Environmental Medicine	**Disagree.** At the outset, it is noted that the definition of the term "Evidence-based," as contained in section 9792.20(e) (formerly subdivision (d)), was not revised. Because some of the comments submitted by the public addressed	None.

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	very proud of the extensive effort they have made over the last several years to build what is arguably the finest infrastructure in existence for the development of occupational medicine guidelines. Commenter states that the new and improved methodology involves literally thousands of hours of effort by a large development team that includes more than 50 physicians, as well as a full-time administrative staff. Commenter indicates at the heart of their work is the creation of a completely transparent, state-of-the-art methodology that adheres to all of the recognized standards for evidence based medicine, including those developed by AMA and AGREE. Commenter states that in evaluating the soundness of a methodology, he hopes that DWC will put a premium -- as ACOEM does – on two fundamentals: Evidence must be subjected to a clearly articulated, consistent, valid and reliable grading system, and in order to be valid, that system must evaluate, grade and critique the entire body of high and moderate quality literature on a topic. Commenter states that of all the evidence, quality randomized clinical trials and crossover trials should be the standard we strive for as offering the BEST basis for decision-making on what treatments are effective for the care of injured workers. Commenter states finally -- and again, in the best long-term interests of the State of California -- he urges DWC to place a premium going forward on guidelines that offer original evaluations of quality studies of injured workers as the cornerstones of the methodology.	Association, A Component Society of ACOEM August 12, 2008 Written and Oral Testimony	the evidence-based concept, DWC considered it important to respond to these comments. Thus, these comments have been grouped generally under section 9792.20(e). Commenter states that the first principle for any guideline adopted is that it should be truly evidence-based and that guidelines are only as good as the methods used to develop them. Commenter also argues that the methodology should adhere to all of the recognized standards for evidence-based medicine, including those developed by AMA and the AGREE Instrument. The comment addresses the rigor upon which a medical treatment guideline has been developed, and specifically as it applies to the ODG guidelines. This issue was addressed by the review of RAND in its 2005 Report and both ACOEM AND ODG met RAND's review. Specifically, it is noted that the ODG guidelines complied with the AGREE Instrument domain of Rigor. The DWC determined that the ODG guidelines met the requirements of the statute based on the findings of the 2005 RAND Report as stated in the ISOR, p. 40. RAND used the AGREE Instrument to evaluate the ODG guidelines. (2005 RAND Report, at p. xix.) The Agree Instrument	

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			addresses six domains that suggest an unbiased guideline (AGREE Collaboration, 2001). These six domains include Rigor of Development, which determines "whether developers used systematic and explicit methods to search for evidence and formulate recommendations, considered potential health benefits and risks, had the guideline externally reviewed, and provided an updating plan." The 2005 RAND Report rated the ODG's Rigor of Development "very good." (2005 RAND Report, at p. xx.) ODG's Appendix B—ODG Treatment in Workers' Comp, Methodology Description Using the AGREE Instrument, which has been added to the rulemaking file, describes ODG's Rigor of development, in relevant part, as follows: "ODG Treatment is based on a comprehensive and ongoing medical literature review with preference given to high-quality systematic reviews, meta-analyses and clinical trials."	
9792.20(f) Functional Improvement Definition	Commenter questions how claim adjusters will interpret the proposed definition of the term "functional improvement" in §9792.20(f). Commenter states that as amended, functional improvement now means "… quantifiable improvement in activities of daily living...." Commenter questions how will this be interpreted by the claim adjuster, or by the physician, for that matter? Commenter asks how are activities of daily	Sue Borg, President California Applicants' Attorneys Association Written & Oral August 12, 2008	**Agree.** Originally, the definition of the term "functional improvement" was defined to mean either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part	Section 9792.20(f) is amended as follows: (~~e~~f) "Functional improvement" means either a ~~clinically significant quantifiable~~ clinically significant improvement in activities of daily living or a reduction in work restrictions as

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	living *quantified*? Commenter questions if a worker has less trouble walking, or climbing stairs, or carrying objects, or performing daily grooming, *etc.*, is that a "*quantifiable*" improvement in activities of daily living? Commenter believes this change will cause unnecessary problems as claim adjusters struggle to figure out how to *quantify* the improvement in ADLs and deny requested treatments in the meantime. Commenter urges that the change to this section be deleted, and that the current language which requires a "clinically significant" improvement be retained.		of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to sections 9789.10-9789.111; and a reduction in the dependency on continued medical treatment." That definition was subsequently changed to substitute the words ***"clinically significant"*** with the word ***"quantifiable."*** Many comments have been submitted stating that functional improvement may not actually be quantifiable and therefore the term "clinically significant" may be more appropriate, and easier to be communicated by the treating physician in the reports. Therefore, the definition of functional improvement will be reverted to the original definition as contained in the original draft.	measured during the history and physical exam, performed and documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to ~~S~~sections 9789.10-9789.111; and a reduction in the dependency on continued medical treatment.
9792.20(f) Functional Improvement Definition	Commenter is concerned the DWC has overlooked a critical aspect of successful medical recovery in its use of "functional improvement." Commenter states "functional improvement" is used repeatedly throughout the MTUS as the sole or threshold criteria for continuing medical treatment. Commenter states while no one would argue functional improvement can be a fundamental measure of the efficacy of treatment, he suggests that the DWC has inadvertently omitted addressing the fact that therapies of many types and under many chronic circumstances are extremely successful, vital in fact, if they maintain function. Commenter states in other words, when therapy is diminished or withdrawn, the result is instability, deterioration and less functionality. Commenter indicates examples include kidney	Stephen J. Cattolica AdvoCal August 7, 2008 Oral Comment August 12, 2008	**Agree in part. Disagree** with the comment that the Chronic Pain Medical Treatment Guidelines misuses the term "functional improvement." The use of the definition of the term "functional improvement" is appropriate. The definition of the term "functional improvement" will be applicable to specific treatments as set forth in the MTUS, such as use of acupuncture for musculoskeletal conditions. It is clear from the text of the proposed regulations that this definition will not apply to conditions that do not result in a	The first and second paragraphs under the subtitle "Pain Outcomes and Endpoints" at page 8 of the Introduction of the Chronic Pain Medical Treatment Guidelines, are amended as follows: The last sentence of the first paragraph under the subtitle "Pain Outcomes and Endpoints" at page 8, is deleted as follows: ~~Moreover, "[t]he desired end~~

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	dialysis, stretching exercises, strength training and cardiovascular exercises. Commenter states maintenance of function may not manifest in the form of "quantifiable improvement in (ADL) or a reduction in work restrictions ... and a reduction in the dependence on continued medical treatment," as the definition calls for. Commenter states in fact, as previously pointed out, for some relatively common medical conditions, maintenance of function is almost completely "dependent on continued medical treatment." Commenter states a number of examples of the types of problems that would occur if functional improvement remains the sole criteria for continued authorization can be found within proposed § Post surgical Treatment Guidelines. Commenter cites proposed Section 9792.24.3(c)(3), and argues that in this example at the completion of the general course of therapy, the best that may be possible is maintenance of function. Commenter argues the mandate for functional improvement would then disallow further therapy and thus cause deterioration. Commenter cites proposed Section 9792.24.3(c)(4), and argues that in this example, documentation of functional improvement may not be possible, but documentation of the maintenance of function might. Commenter argues that if so, therapy that is "gradually reduced or discontinued" may be the very reason that the patient does not "gain independence in management of symptoms or achieve a functional goal." Commenter adds that at some point in the treatment of the patient, "achievement of a functional goal" is likely synonymous with the end of the		functional outcome, such as, for example, the treatment of hypertension or the treatment of diabetes where the desired outcome is to control blood pressure and blood sugar. **Agree** with commenter, and as stated above, that there are situations where further functional improvement is no longer possible for the patient, or for when there is a fluctuation or breakthrough pain in the patient's chronic course. Thus, clarification in the Chronic Pain Medical Treatment Guidelines is necessary to address the issue of treatment plan for a chronic condition to maintain the patient's level of function. Language from the California Medical Board was adapted to define the treatment plan for chronic pain and the need for periodic review. The first and second paragraphs under the subtitle "Pain Outcomes and Endpoints," at page 8 of the Introduction of the Chronic Pain Medical Treatment Guidelines were accordingly amended, and a new third paragraph has been added.	~~point in pain management is return to function rather than complete or immediate cessation of pain." (ACOEM Practice Guidelines, 2nd Edition, p. 116)~~ The second paragraph under the subtitle "Pain Outcomes and Endpoints" at page 8, is amended as follows: "The p~~P~~hysician~~s~~ treating in the workers' compensation system must be aware that just because an injured worker has reached a permanent and stationary status or maximal medical improvement does not mean that they are no longer entitled to future medical care. The physician should periodically review the course of treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of pain management depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current

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	program, but not the end of what may be necessary for the patient to maintain a satisfactory level of function. Commenter cites proposed Section 9792.24.3(c)(4)(A), and argues that the exacerbation could occur outside the post surgical physical medicine period and thus disallow necessary treatment. Commenter cites proposed Section 9792.24.3(c)(4)(B), and argues that the situation described in this subdivision is the epitome of the problem being described. Therapy can bring a patient to an improved, but maintenance level, yet the guideline completely ignores the possibility of deterioration if therapy is diminished or discontinued as this paragraph suggests. Commenter argues maintenance of a level of function might be considered part of the definition of "Maximum Medical Improvement" (MMI). Commenter states that if so, following this functional improvement mandate, while in the process of settling a claim, could cause deterioration and loss of function at the most critical point of that process. Commenter indicates the DWC must carefully expand possible post surgical therapies to include those that maintain function as individual situations dictate.			treatment plan and consider the use of other therapeutic modalities. When prescribing controlled substances for pain, satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. (http://www.medbd.ca.gov/pain_guidelines.html)." A new third paragraph is inserted as follows: "Additionally, fluctuations are likely to occur in the natural history of patients with chronic pain. Exacerbations and "breakthrough" pain may occur during the chronic clinical course and adjustments to the treatment will be necessary."
9792.20(f) Functional Improvement Definition	Commenter questions the applicability of the definition of "functional improvement." Commenter indicates his concern is regarding cases where the injured worker needs relevant ongoing medical care in order to maintain the functional improvement already made. Commenter states for example, while their two implantable therapies, (e.g., spinal cord stimulation and intrathecal drug pumps) are reserved for relatively late in the treatment continuum and are primarily	N. William Fehrenbach, Director, State Government Affairs Medtronic August 10, 2008	**Agree in part. Agree** with the comment that the physician treating in the workers' compensation system must be aware that just because an injured worker has reached a permanent and stationary status or maximal medical improvement, this does not mean that that the injured	The Introduction, under the subject "Pain Outcomes and Endpoints" at pages 8-9 is amended as follows: **Pain Outcomes and Endpoints** "Pain is subjective. It cannot

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	focused on providing pain relief, the therapies can and often do directly provide meaningful functional improvement for the patient. Commenter states, however, if the definition of "functional improvement" requires both the first part and second part including "and a reduction in the dependency of continued medical treatment," carriers may construe that to mean that functional improvement has not been achieved (because the person clearly continues to need the implantable device, refills, programming, and replants at the appropriate time). Commenter adds that beyond their therapies, carriers may apply this definition of functional improvement strictly to mean "ongoing further improvement" versus "continued maintenance of functional improvement that has already been achieved beyond baseline." Commenter states that clarification of this requirement is extremely important and supported both by current California statute and case law which requires the provision which requires care that may only relieve pain, and has no requirement for functional improvement (Lab. Code section 4600(a), California Health and Safety Code section 124960). Commenter recommends that §9792.20(f) be amended as follows: "Functional Improvement" means either a clinically significant quantifiable improvement in activities of daily living or a reduction in work restrictions above baseline as measured during the history and physical exam, performed and documented as part of the evaluation and management billed under the Official Medical Fee Schedule (OMFS) pursuant to ~~S~~sections 9789.10-9789.111 defined either by ongoing continued further improvement or the maintenance of already achieved improvement beyond initial baseline; and where possible a reduction in the dependency of continued medical treatment. However, there will nonetheless be circumstances		worker is no longer entitled to future medical care. Thus, pursuant to this comment, the last sentence under the subject "Pain Outcomes and Endpoints" in the Introduction in reference to "functional improvement" was deleted to reflect this concept. **Disagree** with Commenter's suggested clarifying language. It is noted that the purpose of the definition of "functional improvement" is to measure the effects of specific treatments, used for chronic pain. Thus, commenter's remaining suggested changes detract from the intended purpose of the definition of "functional improvement," and therefore the definition is left intact. However, as previously indicated, recognizing Commenter's concern that functional improvement cannot go on indefinitely in some instances but rather in some cases improvement reaches a plateau, DWC has added clarifying language to the Introduction of the Chronic Pain Medical Treatment Guidelines at pp. 8-9, which is adapted from the California Medical Board, which reflects a response to Commenter's concerns.	be readily validated or objectively measured (AMA Guides, 5th Edition, page 566). Furthermore subjective reports of pain severity may not correlate well with its functional impact. Thus, it is essential to understand the extent that function is impeded by pain (AMA Guides, 5th Edition, page 578). ~~Moreover, "[t]he desired end point in pain management is return to function rather than complete or immediate cessation of pain." (ACOEM Practice Guidelines, 2nd Edition, p. 116)~~ "The p~~P~~hysician~~s~~ treating in the workers' compensation system must be aware that just because an injured worker has reached a permanent and stationary status or maximal medical improvement does not mean that they are no longer entitled to future medical care. The physician should periodically review the course of treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification

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	where injured workers have achieved functional improvement and need relevant similar levels of medical treatment in order to maintain the functional improvements that they have already made. Nothing in this definition should be construed to limit a carriers responsibility to provide necessary care to relieve pain."			of pain management depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. When prescribing controlled substances for pain, satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. (http://www.medbd.ca.gov/pain_guidelines.html). "Additionally, fluctuations are likely to occur in the natural history of patients with chronic pain. Exacerbations and "breakthrough" pain may occur during the chronic clinical course and adjustments to the treatment will be necessary."
9792.20(f) Functional Improvement Definition	Commenter indicates that his organization strongly directionally supports DWC's proposal that §9792.24.2 - Chronic Pain Medical Treatment Guideline replace Chapter 6 of the ACOEM Practice Guidelines, 2nd Edition (2004). Commenter states	Eric Hauth, Executive Director Neuromodulation Therapy Access Coalition	**Agree in part.** See response to Stephen J. Cattolica, dated August 7, 2008, above.	See action taken in connection with comment submitted by Stephen J. Cattolica, dated August 7, 2008, above.

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	that his organization, however, has heard of some issues raised by physicians with whom they work regarding overemphasis on Functional Improvement and encourage DWC to review and consider those comments carefully in making its final determination on the proposed rules.	August 12, 2008		
9792.20(h) Medical Treatment Guidelines development/ Methodology	Commenter addresses the methodology in developing the chronic pain medical treatment guidelines. The methodology of development of guidelines addresses directly the concept of "medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). Commenter states a key principle of evidence-based medicine is transparency. Commenter states that there are a number of areas in the proposed revisions to the MTUS in which it would better inform and serve the public to more fully present or disclose additional information. Commenter states with more complete information, the public, providers and workers can more accurately judge the quality of key studies, the quality of the evidence on each topic, the strength of recommendations, and any potential biases in the assessment and related recommendations. Commenter adds this information would allow these groups to better determine the probable effectiveness and reproducibility of the treatments discussed. Commenter suggests it be added to the guideline before the guideline is adopted. Commenter states that the AGREE methodology for evaluation guidelines, which was used by RAND, includes a criterion for the guideline developers and reviewers to disclose all affiliations and potential conflicts of interest within the guideline. Commenter states that he did not see this information for ODG personnel; for the ODG panel that reviewed the evidence, discussed it and assigned strength of evidence and recommendation ratings; or for the MEEAC.	Jeffrey S. Harris, M.D. August 11, 2008	**Agree in part.** At the outset, it is noted that the definition of the term "Medical treatment guidelines," as contained in section 9792.20(h) (formerly subdivision (g)), was not revised. Because some comments submitted by the public addressed the development of medical treatment guidelines in general, and specifically the development of the Official Disability Treatment Guidelines and the Chronic Pain Medical Treatment Guidelines, DWC considered it important to respond to these comments. Thus, these comments have been grouped generally under section 9792.20(h). **Agree** with the comment that transparency is important. Disclosure of Conflicts statements were obtained from the MEEAC members at the inception of the committee, and were updated in the second year. Current copies of the signed and dated Disclosure of Conflicts statements will be made part of the rulemaking file as documents relied upon, and will be posted to DWC's website for the benefit of the public.	The signed and dated Disclosure of Conflicts will be made part of the rulemaking file as documents relied upon, and will be posted to the website at http://www.dwc.ca.gov containing the following pertinent information: Name of MEEAC Member; Medical Specialty; Title/Affiliation; National, Regional, Local Committee Affiliations; Financial/Non-Financial Conflict of Interest; Research Grants and Other Support.

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			Disagree with the comment regarding ODG's Disclosure of Conflicts of Interest. In the Initial Statement of Reasons, DWC indicated that the 2005 RAND Report identified the Work Loss Data Institute's Official Disability Guidelines (ODG) as meeting the requirements of the statute that the guidelines adopted be "Scientific and Evidence-Based, Peer-Reviewed, and Nationally Recognized." (See, Table 4, p. 21; Table 4.2, p. 27.) RAND used the AGREE Instrument to evaluate the ODG guidelines. (2005 RAND Report, at p. xix.) The Agree Instrument addresses six domains that suggest an unbiased guideline (AGREE Collaboration, 2001). These six domains include editorial independence, which determines "whether the guideline is editorially independent from the funding body and conflicts of interest of guideline development members have been recorded." The 2005 RAND Report rated the ODG's editorial independence as "excellent." (2005 RAND Report, at p. xx.) ODG's Appendix B—ODG Treatment in Workers' Comp, Methodology Description Using the AGREE Instrument, which has been added to the rulemaking file, reflects compliance with the AGREE Instrument's domain of editorial	

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			independence, and specifically the requirement that the conflict of interest of guideline development members have been recorded, and are available upon request by email from the ODG Helpdesk, at ODG@worklossdata.com. A request may be made specifying the conflict of interest disclosure about the ODG editorial contributor(s). Commenter is incorrect in asserting that the AGREE Instrument requires publishing of the disclosures within the guidelines.	
9792.20(h) Medical Treatment Guidelines Development/ Literature Search	Commenter submits comments under the subtitle, *Literature Search*. This comment addresses directly the concept of "medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). Commenter states the search terms for each clinical question are not presented in the documentation in the usual matrix, making it difficult to ascertain the completeness and relevance of the search. Commenter further states it appears that only MEDLINE was searched. Commenter states use of a proper MEDLINE, EMBASE, PEDRO and CINAHL search would cover the appropriate databases including those for physical therapy and allied health professions. Commenter adds the ODG material includes materials not generally regarded as evidence, such as guidelines, insurance company coverage policies, and medical device company literature. Commenter opines judging by the number of study abstracts presented in Appendix D compared to other searches, the evidence search was incomplete. Commenter states ODG cites about 220 references. Commenter indicates other guidelines dealing with	Jeffrey S. Harris, M.D. August 11, 2008	**Agree in part. Agree** that an explanation of ODG's ratings should be included with the references which have been incorporated into the regulations in sections 9792.24.2(f), and 9792.24.3(d)(3). Accordingly, a copy of ODG's *Explanation of Medical Literature Ratings,* will be placed in the back of Appendixes D—Chronic Pain Medical Treatment Guidelines Division of Workers' Compensation and Official Disability Guidelines References, and Appendix E— Postsurgical Treatment Guidelines Work Loss Data Institute-Official Disability Guidelines References when the final documents are posted to DWC's website, and/or when provided to the public upon request. This document will also be	A copy of ODG's *Explanation of Medical Literature Ratings,* will be placed in the back of both Appendix D—Chronic Pain Medical Treatment Guidelines Division of Workers' Compensation and Official Disability Guidelines References, and Appendix E— Postsurgical Treatment Guidelines Work Loss Data Institute-Official Disability Guidelines References when the final documents are posted to DWC's website, and/or when provided to the public upon request.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the topic of pain management have located over 1,700. Commenter states that ODG assigns an "a," "b," or "c" to studies as a rating of quality. Commenter states that these ratings are explained on the ODG website, but not in the document. No numerical scoring of study quality against specific criteria as called for in the MTUS methodology or evidence tables is presented. Commenter adds that quantitative, itemized ratings and evidence tables are a widely accepted technique to present study quality assessments for the interested reader [3 Egger M, Smith M, Altman D, eds. *Systematic Reviews in Health Care: Meta-analysis in Context*. London: British Medical Journal Books; 2001. 4 Straus SE, Richardson WS, Glasziou P, Haynes RB. *Evidence-based Medicine: How to Practice and Teach EBM, 3rd edition*. Edinburgh: Elsevier Churchill Livingstone; 2005. 5 Heneghan C, Badenoch D. *Evidence-based Medicine Toolkit, 2nd edition*. Malden: Blackwell Publishing; 2006.] Commenter opines that they should be included in the document.		added to the rulemaking as a document relied upon. **Disagree** with the comment that the ODG guidelines do not comply with the Agree Instrument domain of Rigor of Development, which includes literature search. As indicated above, the DWC determined that the ODG guidelines met the requirements of the statute based on the findings of the 2005 RAND Report as stated in the ISOR, p. 40. As previously indicated RAND used the AGREE Instrument to evaluate the ODG guidelines. (2005 RAND Report, at p. xix.) The Agree Instrument addresses six domains that suggest an unbiased guideline (AGREE Collaboration, 2001). These six domains include Rigor of Development, which determines "whether developers used systematic and explicit methods to search for evidence and formulate recommendations, considered potential health benefits and risks, had the guideline externally reviewed, and provided an updating plan." The 2005 RAND Report rated the ODG's Rigor of Development "very good." (2005 RAND Report, at p. xx.) ODG's Appendix B—ODG Treatment in Workers' Comp, Methodology Description Using the AGREE Instrument, which has been added to the rulemaking file, describes	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			ODG's Rigor of development, in relevant part, as follows: "ODG Treatment is based on a comprehensive and ongoing medical literature review with preference given to high-quality systematic reviews, meta-analyses and clinical trials."	
9792.20(h) Medical Treatment Guidelines Development/ Inclusion Criteria	Commenter submits comments under the subtitle, *Inclusion Criteria.* This comment addresses directly the concept of "medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). Commenter states that the ODG inclusion criteria for studies to consider as potential evidence that he has seen on the ODG website are rather vague. Commenter states that the criteria are not cited in the proposed regulation. Commenter indicates that Inclusion criteria generally go beyond specifying the time frame and language of the material. Commenter submits the following bullet points in support of his argument: • Many guidelines now limit included studies to high quality RCTs for treatment, high quality prospective cohort studies for prevention, causation and harms, and comparison to gold standards for studies of diagnostic tests. The ODG guidelines at various times rely on lower grades of evidence such as lower quality Randomized Controlled Trials (RCTs), case series and case reviews. The latter are generally excluded from high quality guidelines. • The ODG guidelines cite review articles, state guidelines and manufacturer's literature as evidence. Commenter states that these materials are not generally considered evidence in the scientific/EBM community.	Jeffrey S., M.D. August 11, 2008	**Disagree.** Disagree with the comment that the ODG guidelines' inclusion criteria are vague. As indicated above, the DWC determined that the ODG guidelines met the requirements of the statute based on the findings of the 2005 RAND Report as stated in the ISOR, p. 40. Commenter is raising the very same issue of Rigor of Development, which has been addressed above. The Inclusion Criteria is one of the elements considered under the Rigor of Development domain of the AGREE Instrument. This element was considered by RAND in issuing its evaluation of the ODG guidelines in its 2005 Report.	None.
9792.25(c)(1)/ Critical Appraisal of Quality of	Commenter submits comments under the subtitle, *Critical Appraisal of Quality of Individual Studies*. This comment addresses directly the development of	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** DWC acknowledges that the ODG guidelines do not contain the same MTUS methodology.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Individual Studies	"medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). Commenter states that it is not clear how ODG critically appraised the studies and other materials used as evidence. Commenter states that the ranking scheme used and the three levels of quality assigned are not standard for evidence-based medicine. Commenter submits the following bullet points in support of his argument: "• Commenter states ODG presents a rank ordering of types of studies on its website as equivalent to strength of evidence. Commenter states this is not part of the MTUS methodology or generally accepted in the EBM literature. Commenter adds it is not correct that study design is equivalent to quality or robustness, since studies within a design type vary widely in robustness of design and quality of execution." "• Commenter states the type of study specified in the MEDLINE abstracts ODG reprints is incorrectly labeled in a significant number of cases. Commenter indicates a quantitative evaluation of each study is needed to determine quality." " • Commenter states ODG's published scheme to rate study quality, which was taken from the Cochrane Handbook according to the footnote, should apply only to randomized controlled trials (RCTs). Commenter opines this rating scheme is out of date. Commenter adds that the Cochrane Back Group has since updated the scheme to make it quantitative, reducing variability." "• Commenter states this older Cochrane scheme specifies a series of criteria to detect potential study bias. Commenter indicates these criteria are used to prepare evidence tables so that the reader can follow the critical appraisal and understand its validity. Commenter states there is no evidence tables presented. Commenter opines they should be		The strength of evidence as adopted in § 9792.25(c) is not applicable to the DWC selection of guidelines to adopt into the MTUS. This is necessary because there is no consensus of a specific evidence rating system, and the ACOEM rating system is unique to ACOEM. If DWC were to only use ACOEM's rating system in its evaluation of guidelines to supplement the MTUS, DWC would be precluded from using any guidelines and would be limited solely to the ACOEM guidelines. The Labor Code allows for the use of other guidelines as Labor Code section 4604.5(e) provides that "for all injuries not covered by the … official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence based medical treatment guidelines generally recognized by the national medical community and that are scientifically based." With regard to commenter's assertion that ODG's grading system is not "generally accepted in the evidence-based medicine (EBM) literature," DWC disagrees. In this regard, it is noted that EBM is still being developed and a consensus has yet to be reached. Different organizations have different systems. For example, the	

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	included." "• Commenter states ODG also appears to be applying the scheme to all types of "evidence," including systematic reviews, meta-analyses, observational studies, case series, case reports, and other organizations' guidelines. Commenter states the scheme was not designed to evaluate any of these types of studies. Commenter indicates there are separate systems for each type of study."		American Academy of Orthopedic Surgeons, the American Academy of Neurology, and the American College of Physicians, are some examples of organizations using different systems. With regard to commenter's assertions that ODG does not rate studies but abstracts, it is noted that ODG's website indicates that "Full text copies of [the] studies are used by physician editors in formulating recommendations and are available on request. ODG is continuously updated reflecting the findings of new studies as they are conducted and released; subscribers are always up to date." Thus, commenter's assertions are without merit. (Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers' Comp, Methodology Description using the AGREE Instrument, under section entitled Rigor of Development. (Appendix B)). With reference to commenter's statements that the Cochrane Group has since updated their published rating methodology and that ODG has not adopted it and that ODG includes systematic reviews, meta-analyses, observational studies, case series, case reports, and other organizations' guidelines in their	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			reviews, it is noted again that EBM is still being developed and a consensus has yet to be reached. Different organizations have different systems. Moreover, the MTUS rating methodology as adopted from ACOEM in 2007 includes systematic reviews as evidence.	
9792.25(c)(1)/ Strength of the Body of Evidence	Commenter submits comments under the subtitle, *Strength of the Body of Evidence*. This comment addresses directly the development of "medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). Commenter states the strength of the body of evidence supporting each recommendation is not specified for most recommendations. Commenter indicates no alphabetical designations of strength and basis are presented for ODG recommendations as required by the MTUS methodology. Commenter submits the following bullet points in support of his argument: "• Commenter states there is no labeling of evidence-based v. consensus based, as there is in the MTUS scheme." "• Commenter states a few recommendations state there is "strong" evidence for the recommendation, for example for exercise, but the term "strong" is not defined." "• Commenter states recommendations in evidence-based medicine discuss the balance between benefits and harms of proposed treatments. Commenter adds this is reflected in the MTUS methodology."	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree**. See response to comment submitted by same commentor on section 9792.25(c)(1)/Critical Appraisal of Quality of Individual Studies, with regard to application of MTUS rating methodology, above.	None.
9792.20(h) Medical Treatment Guidelines Development/ Recommendations	Commenter submits comments under the subtitle, *Recommendations*. This comment addresses directly the development of "medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). Commenter states recommendations generally follow a balanced discussion of the benefits,	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** Disagree with the comment that the ODG guidelines are not clear with respect to the recommendations. As indicated above, the DWC determined that the ODG guidelines met the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	risks and harms of tests, preventive measures and treatments. Commenter also states these explicit discussions also underlie the determination of the net strength of the evidence as positive, indeterminate or negative. Commenter indicates the discussions and recommendations that follow are the product of consideration of the evidence by trained, highly qualified interdisciplinary expert panels, as noted in the AGREE methodology. Commenter adds at times differences of expert opinion among panel members are cited. Commenter states such discussions do not appear in the ODG material. Commenter indicates there are statements about risks, harms and lack of efficacy or functional improvement embedded in the ODG material, but the sources are not generally cited, and there is no consideration of net balance. Commenter submits an example is in the section on opioids for chronic pain. Commenter further states the DWC stated the MEEAC did not reassess the ODG material unless a treatment was labeled "under study." Commenter indicates the clinician in search of guidance to improve net patient outcomes is left with a series of statements with no synthesis or outcome other than "recommended" or "not recommended."		requirements of the statute based on the findings of the 2005 RAND Report as stated in the ISOR, p. 40. As previously indicated, RAND used the AGREE Instrument to evaluate the ODG guidelines. (2005 RAND Report, at p. xix.) The Agree Instrument addresses six domains that suggest an unbiased guideline (AGREE Collaboration, 2001). These six domains include Clarity and Presentation, which determines "whether the guideline makes specific and unambiguous recommendations, presents management options clearly, and includes application tools." The 2005 RAND Report rated the ODG's Clarity and Presentation as "excellent." (2005 RAND Report, at p. xx.)	
9792.21 MTUS-Comorbidities Provision	Commenter states for the average patient, the proposed MTUS generally reflects proper treatment protocols. Commenter adds an individual patient's recovery, however, is influenced by prior history, comorbidity, traumatic causation, ergonomic and environmental conditions, age, fitness and psychosocial factors. Commenter opines language should be added to clarify injured workers with complicating factors may need more treatment. Commenter states without such a statement, insurance companies will give no special consideration for injured workers with complicated cases. Commenter suggests the MTUS should take into consideration comorbidities by adding the following language to §	David Benevento, DC, President California Chiropractic Association August 12, 2008	**Agree in part. Disagree** that a new separate subdivision should be added to the MTUS addressing comorbidities as this was not part of the 45-day notice, and commenter does not address the evidence-based analysis issue. **Agree** that complexities of the patient's conditions and circumstances that warrant additional treatment should be taken into consideration in providing medical treatment if	Paragraph 4, page, 8, of the section subtitled: ***Functional Restoration Approach* to the Chronic Pain Management** of the Introduction, of the Chronic Pain Medical Treatment Guidelines has been amended as follows: "Using medications in the treatment of pain requires a thorough understanding of the mechanism underlying the pain as well as to identify

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	9792.21: *"(d) Treatment shall not be denied if the complexity of the patient's condition and circumstance warrants additional treatment, as documented by the treating physician."*		evidence-based. The complexities of the patient's conditions are addressed in various sections of the MTUS such as the Chronic Pain Medical Treatment Guidelines and the Postsurgical Medical Treatment Guidelines. Clarifying language in this regard has been added to the Chronic Pain Medical Treatment Guidelines in the section subtitled: ***Functional Restoration Approach* to the Chronic Pain Management** of the Introduction, at page 8.	comorbidities that might predict an adverse outcome. As stated on page 47 of the ACOEM Practice Guidelines, '[c]onsideration of comorbid conditions, side effects, cost, and efficacy of medication versus physical methods and provider and patient preferences should guide the physician's choice of recommendations.' Choice of pharmacotherapy must be based on the type of pain to be treated and there may be more than one pain mechanism involved. The physician should also tailor medications and dosages to the individual taking into consideration patient-specific variables such as comorbidities, other medications, and allergies. When effective, medications provide a degree of analgesia that permits the patients to engage in rehabilitation, improvement of activities of daily living, or return to work. There are no drugs that have been proven to reverse, cure, or "heal" chronic pain ~~or neuropathic~~. Periodic review of the ongoing chronic pain treatment plan for the injured worker is essential according

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				to the Medical Board of California Pain Guidelines for controlled substances."
9792.21(c)	Commenter references §9792.21(c). Commenter questions whether this section is too stringent. Commenter questions whether this section allows for medical standards of practice based on consensus.	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Disagree.** Comment is non responsive.	None.
9792.22 Restructuring	Commenter supports the general approach restructuring of the MTUS.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree.**	None.
9792.23 Restructuring	Commenter supports the restructuring of the MTUS that facilitates topic-by-topic update adoption.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree.**	None.
9792.23 Restructuring	Commenter states ACOEM supports the proposed reorganization of the MTUS to make it more user-friendly and to allow the DWC to adopt and/or update portions of the MTUS through formal rulemaking without affecting other parts of the MTUS.	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree.**	None.
9792.23 Restructuring	Commenter supports the proposed reorganization of the MTUS to make it more user-friendly and to allow the DWC to adopt and/or update portions of the MTUS through formal rulemaking without affecting other parts of the MTUS.	Steven C. Schumann, M.D., Legislative Chair Western Occupational & Environmental Medicine Association, A Component Society of ACOEM August 12, 2008	**Agree.**	None.

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		Written and Oral Testimony		
9792.23(b)	Commenter recommends Section 9792.23(b) be changed to replace the word "treatment" with the words "conditions or injuries." Commenter states this language conforms to Labor Code section 4604.5(e), which requires authorized treatment to be in accordance with other scientifically and evidence based medical treatment guidelines for all injuries not covered by the MTUS, and section 9792.25(b) of the regulations.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree.** Commenter is correct that the language in section 9792.23(b) should be consistent with the statute (Lab. Code, §4604.5(e)), and with the regulations (§9792.21(c), §9792.25(b), and §9792.25(c)(1)). Section 9792.23(b) will be amended to substitute the word "treatment" with the words "conditions or injuries."	Section 9792.23(b) is amended as follows: "For all ~~treatment~~ conditions or injuries not addressed in the MTUS, the authorized treatment and diagnostic services in the initial management and subsequent treatment for presenting complaints shall be in accordance with other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community pursuant to section 9792.25(b)."
9792.23(b)	Commenter recommends § 9792.23(b) be revised to substitute the word "treatment" with the word "injuries" at the beginning of the sentence. Commenter states this change is needed in order to be consistent with Labor Code §4604.5(e), which requires authorized treatment to be in accordance with scientific and evidence-based medical treatment guidelines for all *injuries*.	Marie W. Wardell Claims Operations Manager State Compensation Fund August 12, 2008	**Agree.** See response to Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, above.	Section 9792.23(b) is amended as reflected above.
9792.23(b)(1) Clinical Topics/Chronic Pain Guidelines Clarity	Commenter states section 9792.23(a) defines what is included within the MTUS, while 9792.23(b) defines how treatment can be appropriately requested when the diagnosis, requested treatment, or circumstances surrounding the injury are not addressed by a guideline found within the MTUS. Commenter states paragraph (b)(1) begins with a conditional phrase which renders the remainder of the sentence confusing and misleading.	Stephen J. Cattolica AdvoCal August 7, 2008 Oral Comment August 12, 2008	**Agree in part**. **Agree** with the comment that Section 9792.23(b)(1) is not clear as to when the Chronic Pain Medical Treatment Guidelines apply when other guidelines are being used. Commenter's suggestion that the definition of the term "chronic pain" be used as a transition to the	Section 9792.23(b)(1) has been amended as follows: "In providing treatment using other guidelines pursuant to subdivision (b) above and in the absence of any ~~surgical options for the complaint~~ definitive

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	Commenter indicates the chronic pain guidelines already are part of the MTUS, by definition, since they appear in sequence with 9795.23.1. Commenter opines the initial phrase of (b)(1) is unnecessary and misleading. Commenter believes this initial statement confuses the issue and begs the question why a surgical option or the lack of it, has anything to do with the applicability of the chronic pain guidelines. Commenter opines section 9792.23 (b)(1) should be deleted. In the alternative, commenter suggests the following language: "If the complaint satisfies the definition of chronic pain as found in Section 9792.20(c), the chronic pain medical treatment guidelines in section 9792.24.2 shall apply."		guideline is appropriate. Section 9792.23(b)(1) has been corrected accordingly. **Disagree** with the remaining comment as DWC believes that it is important to have a transition point between other guidelines and the Chronic Pain Medical Treatment Guidelines.	treatment, ~~in~~ for the patient ~~with chronic pain~~ who continues to have pain that persists beyond the anticipated time of healing, the chronic pain medical treatment guidelines in section 9792.24.2 shall apply."
9792.23(b)(1) Clinical Topics/Chronic Pain Guidelines Clarity	Commenter opines the current language in 9792.23(b)(1) would require an injured worker subject to other pain guidelines would have to undergo surgery before being allowed any other form of pain management. Commenter states that the regulations should be clarified to ensure that an injured worker who does not want to undergo surgery still has access to other forms of reasonable chronic pain management medical treatment. Commenter recommends that the phrase "and in the absence of any surgical options" be deleted from this section.	David Bryan Leonard, Attorney Law Offices of David Bryan Leonard, ALC August 4, 2008	**Agree in part**. See response to Stephen J. Cattolica, AdvoCal, dated August 7, 2008, above.	See action taken in connection with comment submitted by Stephen J. Cattolica, AdvoCal, dated August 7, 2008, above.
9792.23(b)(1) Clinical Topics/Chronic Pain Guidelines Clarity	Commenter states that upon careful examination of § 9792.23. Clinical Topics, he believes that there is potential confusion regarding when the Chronic Pain chapter would apply. Commenter states paragraph (b)(1) begins with an initial assumption that renders the remainder of each confusing and somewhat misleading. Commenter indicates this initial phrase confuses the issue and begs the question why a surgical option or the lack of it, has anything to do with the applicability of the chronic pain guidelines.	N. William Fehrenbach, Director, State Government Affairs Medtronic August 10, 2008	**Agree in part**. See response to Stephen J. Cattolica, AdvoCal, dated August 7, 2008, above.	See action taken in connection with comment submitted by Stephen J. Cattolica, AdvoCal, dated August 7, 2008, above.

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	Commenter states it specifically could cause further confusion. While it seems to exclude use of the Chronic Pain chapter if there are surgical options, yet both of their implantable devices are in fact surgical options appropriately found in the Chronic Pain chapter. Commenter opines the paragraph may be unnecessary and should be deleted. In the alternative, commenter offers the following revised language: "(b)(1) If the complaint meets the definition of chronic pain as found in Section 9792.20(c), the chronic pain medical treatment guidelines in section 9792.24.2 shall apply."			
9792.23(b)(2) Clinical Topics/Postsurgical Guidelines Clarity	Commenter states the post surgical guidelines are part of the MTUS by definition, thus section 9792.23(b)(2) is not necessary. Commenter also notes that as currently proposed, §9792.23 (b)(2) seems to preclude any post-surgical treatment other than post surgical physical therapy (PT). Specifically, commenter states that it appears that after a surgery, PT is all that would be allowed and nothing else is presumed correct. Commenter states there are numerous examples where this strategy is incorrect. Commenter suggests the following revised language if the section is to be retained: "If a surgery is performed, the post surgical treatment guidelines in section 9792.24.3 for post surgical physical medicine shall apply *together with any other applicable treatment guideline found within the MTUS or in accordance with Section* 9792.23 *(b)."*	Stephen J. Cattolica AdvoCal August 7, 2008 August 12, 2008 Oral Comment	**Agree.** Commenter's suggestion is accepted to clarify that postsurgical treatment does not preclude MTUS treatment.	Section 9792.23(b)(2) is amended as follows: "(2) In providing treatment using other guidelines pursuant to subdivision (b) above and if surgery is performed, the postsurgical treatment guidelines in section 9792.24.3 for postsurgical physical medicine shall apply together with any other applicable treatment guidelines found in the MTUS or in accordance with section 9792.23(b)."
9792.23.3(a) Elbow	Commenter agrees with DWC's proposal to adopt updated guidelines for elbow disorders developed by ACOEM. Commenter believes that their elbow update guidelines represent the state of the art in speeding recovery for injured workers through evidence-based care. Commenter states that the new Elbow Disorders chapter includes detailed descriptions of numerous	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree.**	None.

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	treatments, reviews of surgical procedures for the elbow, an expanded physical examination section to improve diagnostic accuracy and an in-depth review of medications used to treat elbow conditions.			
9792.23.3(a) Elbow	Commenter supports the adoption of the ACOEM's new elbow section.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree.**	None.
9792.23.3(a) Elbow	Commenter is delighted the Division proposes to adopt updated guidelines for elbow disorders developed by ACOEM, and looks forward to their continued collaboration with the Division and the State of California to ensure that injured workers receive quality medical care.	Steven C. Schumann, M.D., Legislative Chair Western Occupational & Environmental Medicine Association, A Component Society of ACOEM August 12, 2008 Written and Oral Testimony	**Agree**.	None.
9792.23.5	Commenter references §9792.23.5 and questions whether DWC has adopted the ACOEM Practice Guidelines for treatment of low back pain.	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Agree in part**. **Agree** that the chapter being adopted is the Low Back Complaints, which is contained in the ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 12). This chapter was part of the MTUS regulations when the regulations became effective on June 15, 2007. The adoption and incorporation of this chapter on a chapter-by-chapter basis, as part of this proposed regulatory action, allows the DWC to revise and/or replace the low back complaints	None.

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			guideline independently from other sections of the MTUS for future revisions. **Disagree** with the comment questioning whether DWC has adopted the ACOEM Practice Guidelines for treatment of low back pain**.** DWC has not adopted ACOEM's Revised Low Back Disorders (Chapter 12), issued December 1, 2007.	
9792.23.5(d)	Commenter notes that there is no surgical option provided under this section and questions if this is something the Division will consider in the future. Commenter supports the use of evidence-based guidelines and would like to work with the Division in developing guidelines for the surgical treatment of chronic low back pain thought to be due to degenerative disk disease. Commenter wants to present evidence to the division, scientific evidence, to allow for multiple surgical options of the treatment of degenerative disk disease in the lumbar spine, one of which could include the use of artificial disks. Commenter believes that this type of procedure may be an alternative to fusion surgery for selected patients.	Gerald Rogan, M.D. Musculoskeletal Clinical Research Associates, LLC Oral Testimony August 12, 2008	**Disagree.** The subject of the comment does not address the substance of the proposed regulations. Lumbar surgery is a medical treatment topic to be addressed in the clinical topic section of low back pain which will be addressed by the DWC in a future formal rulemaking. DWC has limited the chronic pain medical treatment guidelines to exclude topics that will be better covered under the clinical topics sections.	None.
9792.24.1 Acupuncture/ Clarity	Commenter states the proposed amendments to this section contain circular references both to other sections of the proposed MTUS regulations and to the draft *Chronic Pain Medical Treatment Guidelines*. Commenter states this circularity renders the whole series of references unusable. Commenter states it is therefore impossible to fully comment on the proposed regulations—in the aggregate—as they pertain to the utilization of acupuncture. Commenter references, subsection 9792.24.1(b)(1), which states: "*These guidelines apply to acupuncture or acupuncture with electrical stimulation when*	William F. Mosca, Lac Executive Director California State Oriental Medical Association August 12, 2008	**Agree in part.** When reorganizing the MTUS by separating the chapters into different sections and adopting them separately, this affected the Acupuncture Medical Treatment Guidelines. Commenter is correct that language needed to be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where	§ 9792.23.1(b) has been amended as follows : "(b) In the course of treatment for neck and upper back complaints where acupuncture or acupuncture with electrical stimulation is being considered, the acupuncture medical treatment guidelines in section 9792.24.1 shall apply and supersede the text in the

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	indicated in the clinical topic medical treatment guidelines in the series of sections commencing with 9792.23.1 et seq., or in the chronic pain medical treatment guidelines (DWC 2008) contained in section 9792.24.2." Commenter states that referencing section 9792.23.1 et seq., each section, in turn, refers back to section 9792.24.1. Commenter offers the example of subsection 9792.23.1(b), which states: *"In the course of treatment for neck and upper back complaints where acupuncture or acupuncture with electrical stimulation is being considered, the acupuncture medical treatment guidelines in section 9792.24.1 shall apply."* Commenter states that at no point in this circular reference scheme does the proposed regulations clearly articulate the range of conditions for which the utilization of acupuncture is appropriate and indicated. Commenter adds that there are some non-specific indications for acupuncture within the existing definitions of the terms *acupuncture* and *acupuncture with electrical stimulation*, but it is far from clear if these are intended as the full extent of intended indications. Commenter adds that similarly, the proposed *Chronic Pain Medical Treatment Guidelines* are circularly referential with respect to the proposed section 9792.24.1. Commenter states that section 9792.24.1 references section 9792.24.2 for the use of acupuncture in chronic pain. Commenter states that section 9792.24.2, in turn, references the proposed *Chronic Pain Medical Treatment Guidelines.* Commenter adds that these guidelines then state:		acupuncture is addressed. Accordingly the phrase "and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture" has been inserted in subdivisions (b) in §§ 9792.23.1 Neck and Upper Back Complaints, 9792.23.3 Elbow Disorders, 9792.23.4 Forearm, Wrist, and Hand Complaints, 9792.23.5 Low Back Complaints, 9792.23.6 Knee Complaints, 9792.23.7 Forearm, and Ankle and Foot Complaints. Moreover, we are replacing the word "indicated" with the word" referenced" in the Acupuncture Medical Treatment Guidelines at section 9792.24.1(b)(1) for clarity purposes. The word "indications" carries a medical usage which is not the intention in this context. The intention here is to reference one section of the MTUS with another. That is, to reference the acupuncture guidelines as applied to the specific clinical topic guidelines. **Disagree** with the remainder of commenter's comments as it is not the intention of the DWC to amend the Acupuncture Medical Treatment Guidelines other than to reorganize the MTUS into a chapter by chapter basis.	ACOEM chapter referenced in subdivision (a) above relating to acupuncture." The same amendment is reflected in the following subdivisions (b) of the following sections: 9792.23.3 Elbow Disorders, 9792.23.4 Forearm, Wrist, and Hand Complaints, 9792.23.5 Low Back Complaints, 9792.23.6 Knee Complaints, 9792.23.7 Ankle and Foot Complaints. § 9792.24.1(b)(1) has been amended as follows: "These guidelines apply to acupuncture or acupuncture with electrical stimulation when ~~indicated~~ referenced in the clinical topic medical treatment guidelines in the series of sections commencing with 9792.23.1 et seq., or in the chronic pain medical treatment guidelines contained in section 9792.24.2."

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	"Section 9792.24.1… addresses the use of acupuncture for chronic pain in the workers' compensation system in California." Commenter urges the Administrative Director to remedy these circular references and reopen the *entirety* of the proposed regulations pertaining to acupuncture for public comment so that he may understand the aggregate intent of these changes before commenting in full.			
9792.24.1 Acupuncture/ Clarity	Commenter states Section 9792.24.1 proposes to eliminate the following language from existing regulation: *"The Acupuncture Medical Treatment Guidelines set forth in this subdivision shall supersede the text in the ACOEM Practice Guidelines, Second Edition, relating to acupuncture, except for shoulder complaints, and shall address acupuncture treatment where not discussed in the ACOEM Practice Guidelines."* Commenter states the elimination of this language obscures these two guidelines and once again exposes injured workers to the inconsistent application of these guidelines in their treatment. Commenter urges the Administrative Director to restore this language which in the opinion of commenter makes it clear that the Acupuncture Medical Treatment Guidelines supersede the ACOEM Practice Guidelines in the absence of clearly contradictory utilization information in the ACOEM Practice Guidelines.	William F. Mosca, Lac Executive Director California State Oriental Medical Association August 12, 2008	**Agree in part.** See response to same commenter on section 9792.24.1 Acupuncture/Clarity, above.	See action taken in connection with comment submitted by same commenter on section 9792.24.1 Acupuncture/Clarity, above.
9792.24.2 General Positive	Commenter joins with many others from the California workers' compensation medical community in support of the adoption of the Official Disability Guidelines (ODG) from Work Loss Data Institute as presumptively correct for the treatment of chronic pain conditions and its addition to the Medical	Robert R. Thauer, President Alliance for Physical Therapy, Rehabilitation & Medical Technology	**Agree.**	None.

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	Treatment Utilization Schedule (MTUS). Commenter states that its members find that the Work Loss Data Institute provides a superior guideline set for chronic pain. Commenter opines that to providers who use evidence-based medicine in their every day practice, ODG's regular updates that reflect the findings of new studies, treatment options and technologies are very valuable.	August 8, 2008 August 11, 2008 Written and Oral Comments		
9792.24.2 General Positive	Commenter states that Boston Scientific Corporation is a worldwide developer and manufacturer of medical devices and has advanced the practice of less-invasive medicine across a wide range of medical specialties. Commenter applauds the responsive action taken by the DWC and MEEAC in proposing new chronic pain guidelines based largely on ODG. Commenter states that the DWC's decision to update the proposed MTUS based on ODG versus ACOEM Guidelines is a positive development for chronic pain patients and providers in California. Commenter strongly believes that the newly proposed MTUS will provide greater clarity than existing ACOEM Guidelines in establishing appropriate treatment modalities for patients suffering from work-related injury or illness.	John Hernandez, PhD Vice President, Health Economics and Reimbursement Boston Scientifics Neuromodulation August 12, 2008	**Agree.**	None.
9792.24.2 General Positive	Commenter is a manufacturer of devices - - including neurostimulators and intrathecal drug pumps typically implanted by a small subset of neurosurgeons and anesthesiologists - - that are currently assisting injured workers, and others throughout the country and world, in obtaining relief from chronic, intractable pain after more conservative treatments have failed. Commenter applauds the strong and balanced MEEAC process, and DWC staff for their openness and fair and balanced approach. Commenter states that as they have stated publicly, in their work with states throughout the country they regularly refer agency staff to DWC, and hold DWC out as an example of an incredibly well-informed, thoughtful staff with a great expert physician panel model in place. Commenter	N. William Fehrenbach, Director, State Government Affairs Medtronic August 10, 2008	**Agree.**	None.

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	states they have reviewed the Chronic Pain proposed regulations and overall believe that they directionally are fair and balanced. They also sincerely appreciate that it provides appropriate coverage for various implantable devices used to treat chronic pain when other treatments have failed.			
9792.24.2 General Positive	Commenter expresses his sincere gratitude to the DWC staff and the MEEAC for their fortitude and perseverance in developing this document. Commenter states this truly represents a heroic effort and a vast improvement over the current ACOEM guidelines that have proven to be restrictive, inconsistent with the current practice of pain medicine and a source of immeasurable frustration to physicians and injured workers alike. Commenter states pursuant to Labor Code section 4600(a), employers are responsible to provide medical treatment to an injured worker that is reasonably required to cure or relieve the effects of the industrial injuries. Commenter states the current guidelines have been counterproductive by delaying or denying medical care to injured workers. Commenter opines that these proposed guidelines are fair and balanced and consistent with the scientific literature. (Commenter's further suggestions are placed under the appropriate section numbers in this chart.)	Philipp M. Lippe, M.D. Medical Corporation Consultant August 11, 2008	**Agree.**	None.
9792.24.2 General Positive with DWC's Guidelines and Commenter's Criticism of ACOEM's Chronic Pain & Low Back Chapters	Commenter is an interventional pain physician based in Palmdale, California, and testifies on behalf of himself, his practice and patients, as well as in his role as the current president of the California Society of Interventional Pain Physicians. Commenter states the structure and functioning and balance of the MEEAC committee and its work have been remarkable. Commenter states the dedication, participation, and input from all relevant types of medical specialties who are representing various specialty societies in a fair and balanced manner has	Francis Riegler, M.D., President California Society of Interventional Pain Physicians August 11, 2008 Oral Comment	**Agree in part. Agree** with comment approving the DWC Chronic Pain Medical Treatment Guidelines adapted from the Work Loss Data Institute's Official Disability Guidelines. **Disagree** with comments regarding the ACOEM Chronic Pain Chapter published on August 14, 2008. An explanation of the DWC Chronic Pain Medical Treatment	None.

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	been truly amazing. Commenter states only this type of fair and balanced process could yield a directionally fair approach and proposal. Commenter states his national society has informed him the MEEAC process and the MTUS product stands in stark contrast to the recently updated ACOEM low back and draft chronic pain chapters and related ACOEM processes which neither included formal representation of any of the national medical societies known for being involved in many of the interventions being reviewed, nor do they reflect any relevant substantive evidence-based and expert medical consensus-based comments and conclusions which have subsequently been made by these various relevant expert societies to ACOEM. Commenter states upon request, he can have his national society chapter share with DWC the latest volley of evidence-based comment letters back and forth between national expert societies and ACOEM, all with the upshot that ACOEM has refused to change any of their recommendations. Commenter adds the contrast at DWC and MEEAC in process and subsequent products is really dramatic. Commenter thanks the DWC for steering clear of these unbalanced, overly conservative, updated ACOEM guidelines.		Guidelines' timeline sheds light into the work which went into the development of these guidelines prior to the publication of the update of the ACOEM Chronic Pain Chapter 6 on August 14, 2008. In June 2007, DWC commenced to consider the development of Chronic Pain Medical Treatment Guidelines to supplement the MTUS consistent with the recommendation of the 2005 RAND Report, which identified chronic pain as a priority area. (See 2005 RAND Report, at pp. xxx, and 86.) The DWC commenced work on a chronic pain guideline in 2007 by having the Medical Evidence Evaluation Advisory Committee (MEEAC) search for potential chronic pain guidelines to use as the basis for DWC's chronic pain guideline, taking into consideration that the ACOEM Practice Guidelines (2nd Edition) did sufficiently address chronic pain (2005 RAND Report, at p. xxviii). Since that time, the Work Loss Data's Official Disability Institute Guidelines (ODG)'s Chronic Pain Chapter was identified as meeting the requirements of the statute (Lab. Code, §§ 77.5(a), 4604.5(b), and 5307.27; see, 2005 RAND Report, Table 4, p. 21; Table 4.2, p. 27). Further, by careful application of the requirements of then section	

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			9792.23 (now proposed section 9792.26) the ODG chapter on chronic pain was adapted to use in the California workers' compensation system. Thereafter, following the requirements of public rulemaking procedures, the Chronic Pain Medical Treatment Guidelines were posted to DWC website for forum comments from August 20, 2007 to September 4, 2007, and changes were made based on public comments and the formal rulemaking was commenced. The rulemaking was filed with the Office of Administrative Law on June 17, 2008, and the Notice was published on the Register on June 27, 2008, with the 45-day public comment period ending on August 12, 2008. During this time, ACOEM provided DWC with drafts of its updated Chronic Pain Chapter 6, which continued to evolve with an indeterminate completion date. Long after DWC was into its formal rulemaking process and after extensive work had been performed by MEEAC with the cooperation and input from the regulated public, ACOEM published its updated Chronic Pain Chapter (Chapter 6), on August 14, 2008. It must be reiterated that Chronic pain was identified as a priority topic not	

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			properly addressed in the ACOEM Practice Guidelines (2nd Edition) by the RAND Report in 2005 (at p. xxviii), and the MTUS became effective on June 15, 2007. Thus, the Administrative Director had made it a priority to add a chronic pain guideline to the MTUS as expeditiously as possible. To that end, she charged the Medical Director and the MEEAC to commence work on that guideline immediately after the MTUS regulations were approved by OAL. To commence evaluation of ACOEM's chronic pain chapter at such a late date would have delayed adopting a chronic pain guideline for the State of California for at least another 6 months. DWC is satisfied that its Chronic Pain Medical Treatment Guidelines as revised is an effective medical treatment guideline which complies with the requirement of the applicable statutes. With regard to ACOEM's Revised Low Back Disorders (Chapter 12), issued December 1, 2007, DWC has not adopted that chapter. The chapter that is in effect is the Low Back Complaints chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 12).	
9792.24.2 General Positive	Commenter states Boston Scientific is a worldwide developer and manufacturer of medical devices and	Jessica l. Holmes, Regional Manager,	**Agree in part.** See response to Francis Riegler, M.D., President,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
with DWC's Guidelines and Commenter's Criticism of ACOEM's Chronic Pain & Low Back Chapters	has advanced the practice of less invasive medicine across a wide range of medical specialties. Commenter states the Neuromodulation Division of Boston Scientific is dedicated to the treatment of patients suffering from chronic intractable pain through spinal cord stimulation and established minimally invasive treatment covered by virtually all government and commercial health plans and most workers' compensation programs throughout the United States. Commenter states her company applauds the DWC staff and the physician advisory board in the action taken in proposing new chronic pain guidelines based largely on the Work Loss Data Institute's Official Disability Guidelines. Commenter states that they understand that current California DWC guidelines rely primarily on the American College of Occupational Environmental Medicine Practice Guidelines 2nd Edition 2004, and they have substantial concerns with the recent updates to the low back chapter and draft chronic pain chapter. Commenter states of particular concern are updated ACOEM recommendations against coverage of more than 50 percent of tests, treatments and therapies considered standard practice in the medical community, including spinal cord stimulation. Commenter states the DWC's decision to update the proposed MTUS based on ODG versus ACOEM guidelines is a positive development for chronic pain patients and providers. Commenter states additionally, her company strongly believes the newly proposed MTUS will provide greater clarity than existing ACOEM guidelines in establishing appropriate treatment modalities for patients suffering from work-related injury or illness.	Boston Scientific's Neuromodulation Division, August 11, 2008, Oral Testimony	California Society of Interventional Pain Physicians, dated August 11, 2008, above.	
9792.24.2 General Positive with DWC's Guidelines and	Commenter represents Medtronic. Commenter thanks the DWC staff for their outstanding leadership during the past few years as the DWC sought to strike a fair and balanced approached to the Medical Treatment	Mark Tellez, Therapy Access Senior Manager Medtronic	**Agree in part.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians,	None.

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Commenter's Criticism of ACOEM's Chronic Pain & Low Back Chapters	Utilization Schedule in general, and specifically most recently on the Chronic Pain chapter. Commenter states that the Administrative Director and Medical Director have had an open-door policy whenever they, or any of the implanting physicians with whom they work, had questions, or wanted to provide information. Commenter states that his organization has analyzed the guidelines regarding therapies in which they are involved, and also have spoken extensively with Interventional Pain physicians with whom they work, and all that have reviewed the proposal generally believe that while not perfect, it is directionally strong. Commenter notes the strong, balanced work, and the balanced MEAAC committee, involves work, participation and input from all relevant types of medical specialties who are representing various specialty societies. The active inclusion of various medical professionals and societies no doubt has been key to helping to ensure that end product is balanced. Commenter states this balanced process and product stands in stark contrast to the recently updated ACOEM Low Back and draft Chronic Pain chapters, and related ACOEM processes, which neither included formal representation of any of the national medical societies known for being involved in many of the interventions being reviewed, nor do they reflect any relevant substantive evidence-based and expert medical consensus-based comments or conclusions which have subsequently been made by these various relevant expert societies to ACOEM. Commenter states the contrast is remarkable, and not surprisingly the products vary dramatically.	Neuromodulation Written and Oral Comment August 11, 2008 Sunny Sutton Sr. Regional Manager Medtronic Oral Comment August 12, 2008	dated August 11, 2008, above.	
9792.24.2 General Positive but Update to Latest ODG	Commenter states that the latest version of the ODG section on pain has been updated since the MEEAC last considered its recommendations. Commenter indicates that CMA believes that it is important that	Frank D. Navarro, Associate Director, CES, California Medical	**Agree.** Government Code section 11346.5(a)(3) requires the Notice of Proposed Rulemaking set forth an informative digest, containing	The Chronic Pain Medical Treatment Guidelines as adapted from the Work Loss Data Institute's Official

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Guidelines	the applicable sections of the MTUS also be updated to reflect those changes. Commenter opines that while this may cause a short delay in the adoption of the regulations, CMA believes that the MTUS should reflect the most recent advances in the science of medicine.	Association, Written & Oral Testimony, August 11, 2008 and August 12, 2008	in relevant part, a concise and clear summary of existing laws and regulations, if any, related directly to the proposed action and of the effect of the proposed action and a policy statement overview explaining the broad objectives of the regulation and, if appropriate, the specific objectives. Government Code Section 11346.8(c) prohibits any agency from adopting, amending, or repealing a regulation which has been changed from that which was originally made available to the public pursuant to Section 11346.5, unless the change is "(1) non-substantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action…". Commenter indicates that the latest version of the ODG section on pain has been updated since the MEEAC last considered its recommendations. Commenter indicates that California Medical Association believes that it is important that the applicable sections of the MTUS also be updated to reflect the most recent advances in the science of medicine.	Disability Guidelines (ODG) Treatment in Workers' Comp – Chapter on Pain is revised to adapt a new version dated October 23, 2008. The Work Loss Data Institute has provided its ODG chapter on pain version to the DWC at no cost. The Chronic Pain Medical Treatment Guidelines, Section 9792.24.2, et al., consists of two parts. Part 1: Introduction, and Part 2: Pain Interventions and Treatments. The Chronic Pain Medical Treatment Guidelines replace the ACOEM's Practice Guidelines' Chapter 6—Pain, Suffering, and the Restoration of Function (Chapter 6) relating to chronic pain.

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			DWC agrees with commenter's suggestions. The Notice of Proposed Rulemaking issued in June 2008 put the public on adequate notice that the subject of Chronic Pain Medical Treatment Guidelines as adapted from Work Loss Data Institute's Official Disability Guideline was addressed as part of the formal rulemaking. Specifically, the Notice states at page 11, in relevant part, as follows: "15. Section 9792.24.2—Chronic Pain Medical Treatment Guidelines (DWC 2008) "Section 9792.24.2(a) provides that the Chronic Pain Medical Treatment Guidelines (DWC 2008), consisting of two parts, are adopted and incorporated by reference into the MTUS. It indicates that Part 1 is entitled Introduction, and Part 2 is entitled Pain Interventions and Treatments. This section further provides that the guidelines replace Chapter 6 of the ACOEM Practice Guidelines, 2nd Edition (2004)." Moreover, Part I, of the Chronic Pain Medical Treatment Guidelines, entitled: Introduction, indicates that the guidelines are being adapted from the ODG guidelines as follows: "The chronic pain medical	

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			treatment guidelines consist of two parts. Part 1 is the introduction. Part 2 consists of pain interventions and treatments. With a few exceptions, Parts 2 is primarily an adaptation of evidence-based treatment guidelines, from the Work Loss Data Institute's Official Disability Guidelines (ODG) Treatment in Workers' Comp – Chapter on Pain (Chronic). The version adapted is dated October 31, 2007, and it is being adapted with permission from the ODG publisher. Any section not adapted directly from ODG is labeled '[DWC]'." As previously stated, DWC is precluded from automatically adopting future updates of documents incorporated into a rulemaking without formal rulemaking. (See response to comment submitted by Harry J. Monroe, Director of Government Relations, Coventry Health Care, dated August 12, 2008, above.) However, because DWC has not completed this rulemaking and because the public has received proper notice DWC is able to adapt an updated version of the ODG guidelines. The ODG guidelines version being adapted is dated October 23, 2008. Specific changes will be reflected in the specific treatment topics throughout the	

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			text of the guideline, which will be part of a 15-day notice to the public.	
9792.24.2 General Positive but Update to Latest ODG Guidelines	Commenter states that as the chair of the Senate Committee on Labor and Industrial Relations, she is pleased to know that the DWC is moving forward with additions to the treatment guidelines for California's injured workers. Commenter states that all indications are that DWC's Advisory Committee is working hard to evaluate the available evidence-based guidelines and to integrate all of the best recommendations into the Schedule. Commenter indicates that one would expect that this thorough work takes time and that is why she is writing to DWC. Commenter observes that due to the nature of the regulatory process, there is always an unavoidable delay and as a result, perhaps some "obsolescence" to a regulation's content. Commenter states that she and her committee are aware that the information, references and recommendations found in the Chronic Pain Medical Treatment Guideline may be as much as a year old by the time it is put to use. Commenter states that her committee has been provided information that indicates that since it was first published in October 2007 by the Work Loss Data Institute, the proposed guideline has been updated or changed in a number of important areas. Commenter urges the Division to rapidly evaluate these changes and include the most recent version feasible into the regulation's final language. Commenter opines that by doing so now, the Division will empower medical providers and claims administrators to make good on the efficient delivery of the best care possible. Commenter believes that the delays caused by "information gap" could cause harm to the injured worker and needlessly drive up costs for everyone involved. Commenter points out that since there is no existing chronic pain guideline, the proposed	Carole Migden, Senator, Senate Committee on Labor and Industrial Relations, August 12, 2008	**Agree.** See response to comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.	See action taken in connection with comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.

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	regulation is not replacing or updating any language currently presumed correct. Rather, it is establishing it for the first time. Commenter indicates that her committee believes that California's injured workers and the workers' compensation health care system as a whole would be best served by adoption of the most current version of the published Official Disability Guidelines rather than the version that is currently proposed.			
9792.24.2 General Positive but Update to Latest ODG Guidelines	Commenter states understanding there will be a need for the Medical Evidence Evaluation Advisory Committee (MEEAC) to quickly review the changes and that the proposed regulations may need some changes, his organization believes that: • The Medical Director and the advisory committee could conduct this review expeditiously. • Any revisions to the proposed regulations should only require another 15 day comment period, and the 15 day period may well be necessary for other changes proposed from public comments. • Optimally the Division could quickly review any changes and keep the rulemaking timetable consistent with its original goal to finalize the proposed changes.	Robert R. Thauer, President, Alliance for Physical Therapy, Rehabilitation & Medical Technology August 8, 2008 and August 11, 2008, Written and Oral Comments	**Agree.** See response to comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.	See action taken in connection with comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.
9792.24.2 General Positive but Update to Latest ODG Guidelines	Commenter represents the Advanced Medical Technology Association (AdvaMed), which supports the adoption of the Official Disability Guidelines (ODG) from the Work Loss Data Institute as presumptively correct for the treatment of chronic pain conditions and its addition to the Medical Treatment Utilization Schedule (MTUS). Commenter states providers who use evidence based medicine in their everyday practice benefit from ODG's regular updates which reflect the findings of new studies, treatment options and technologies. Commenter is concerned the DWC has proposed adoption of the October 2007 version of the ODG Chronic Pain chapter. Commenter states that by the	Thomas E. Tremble, Associate Vice President, State Government Relations, AdvaMed, August 8, 2008	**Agree.** See response to comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.	See action taken in connection with comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.

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	time the current rulemaking process is complete, it is likely the October 2007 version will be almost a year old and changes will have been made to numerous sections. Commenter states in fact, since the Division first proposed this guideline it has been updated by ODG more than a dozen times. Commenter understands that changes to the MTUS include a review by the Executive Medical Director's Medical Evidence Evaluation Advisory Committee (MEEAC) followed by a formal rulemaking process. Commenter recommends the Division expedite evaluation of the changes enacted by ODG since this guideline was first proposed and include, in the regulation's final language, the most recent version. Commenter states by doing this, the Division will streamline the utilization review process for this guideline for the foreseeable future. Commenter states for example, if the new version is not adopted, requests for treatment of chronic pain that use updated references from ODG (rather than the October 2007 version), may need to be reviewed and could be needlessly denied, causing delays and driving up costs. Commenter states he recognizes the Division cannot adopt updates as soon as they are published. Commenter indicates however, implementation of the ODG Chronic Pain guideline has yet to take place. Commenter notes the current rulemaking is not replacing or updating any existing guideline, but establishing a future benchmark. Commenter states clearly, the current version of the published guideline would be preferable and more useful than the year-old version currently proposed. Commenter hopes DWC agrees this is a reasonable and appropriate request and will support adopting of the most recent version.			
9792.24.2 General Positive but Update to	Commenter states the DWC proposes to replace ACOEM's chapter on chronic pain with guidelines adapted from the October 31, 2007, version of the	David Benevento, DC, President,	**Agree.** See response to comment submitted by Frank D. Navarro, Associate Director, CES,	See action taken in connection with comment submitted by Frank D.

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Latest ODG Guidelines	Work Loss Data Institute's Official Disability Guidelines (ODG) Treatment in Workers' Comp - Chapter on Pain. Commenter states while California Chiropractic Association (CCA) believes the ODG are more comprehensive and appropriate than ACOEM, the DWC should adopt the current version of the ODG guidelines. Commenter states many of the commonly used treatment approaches in chronic pain have little scientific research, but that is changing month–by-month as new research is published. Commenter indicates if the MTUS is limited to a specific ODG version, the regulations would need to be constantly updated. Commenter adds adopting an older version of ODG will place injured workers in a situation where treatment that has been scientifically proven to be medically necessary by research published after October 2007 will be denied by insurance carriers because the MTUS is outdated. Commenter states injured workers who take their case to the WCAB will get their treatment approved because it is supported by newer evidence, but injured workers who do not know, do not have time or the resources to obtain their necessary care through the system will end up foregoing treatment shown to address their condition, consider alternative – and in many cases more expensive and perhaps not as effective – treatment regimens if available or resign to a life of pain and other potentially disabling conditions.	California Chiropractic Association, August 12, 2008	California Medical Association, dated August 11, 2008, above.	Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.
9792.24.2 General Positive but Update to Latest ODG Guidelines	Commenter states proposed §9792.24.2 replaces Chapter 6 of ACOEM with the DWC's Chronic Pain Medical Treatment Guidelines. Commenter states the introduction to the DWC Guidelines states that it incorporates ODG as of October 31, 2007. Commenter believes the current language of § 9792.24.2 bars California's injured workers from receiving the most current and recognized forms of medical treatment. Commenter indicates ODG is	David Bryan Leonard, Attorney, Law Offices of David Bryan Leonard, ALC, August 4, 2008	**Agree.** See response to comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.	See action taken in connection with comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.

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	constantly changing. Commenter indicates treatment protocols that may have been previously disputed are now recognized as effective. Commenter indicates MTUS's goal of providing effective treatment to obtain the best medical outcomes is critically hampered by a limitation to a specific medical development date. Commenter recommends § 9792.24.2 be modified to include proposed subsection (e) to read as follows: "(e) When a patient is diagnosed with chronic pain and the treatment for the condition is covered by ODG, the August 1, 2008 version is being adapted with permission from the ODG publisher."			
9792.24.2 General Positive but Update to Latest ODG Guidelines	Commenter states she notes in the Notice of Hearing that the DWC used the October 31, 2007 version of the ODG Chronic Pain guidelines. Commenter states it is her understanding the Work Loss Data Institute updates these guidelines occasionally, and some revisions have been adopted since the October 31, 2007 version was published. Commenter states inasmuch as the process for rebutting the adopted MTUS is unnecessarily complicated and burdensome (reference to her comments in our letter to the Division of December 22, 2006 regarding the "strength of evidence" methodology originally in §9792.22(c)(1)), commenter believes it is imperative that the adopted guidelines be based on the most current medical evidence. Commenter requests the DWC review the updates to the chronic pain guidelines issued by the WLDI since October 31, 2007 and incorporate these changes into the adopted Chronic Pain Medical Treatment Guidelines.	Sue Borg, President, California Applicants' Attorneys Association. Written and Oral Testimony, August 12, 2008	**Agree.** See response to comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.	See action taken in connection with comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.
9792.24.2 General/ Compliance with the Statutes-Lab. Code, §§	Commenter states after reviewing both the proposed revised version of the Chronic Pain Medical Treatment Guidelines and their September 2007 comments, it is their opinion that there has been a slight improvement in the guidelines, particularly as	Keith Bateman, Vice President, Property Casualty Insurers Association of America,	**Disagree.** In the ISOR, at p. 40, DWC indicated that the version of the Chronic Pain Medical Treatment Guidelines being	None.

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4604.5(b), 5307.27	they address opioids, but that, overall, the Chronic Pain Medical Treatment Guides are neither responsive to the legislative requirements nor to the concerns expressed by ACIC in its comments submitted last September. Commenter urges the Administrative Director to delay moving forward on the proposed guidelines until the Chronic Pain Treatment Guidelines can be reorganized and compared to the forthcoming ACOEM chronic pain guidelines in terms of their utility and consistency with the legislative intent. Commenter states as the DWC correctly states, L.C. section 5307.27 requires the Administrative Director to adopt a MTUS that is "scientific and evidence-based, peer-reviewed and nationally recognized." Commenter states there is some suggestion in the materials the ODG Chronic Pain Treatment Guidelines are presumed to meet these criteria because RAND listed ODG's guideline set as meeting the criteria. Commenter indicates the RAND Study for the Commission on Health and Safety and Workers Compensation compared guideline sets on a sample of the most common procedures for workers compensation cases. Commenter states treatment of chronic pain was not one of them. Commenter indicates that the statute further provides the MTUS at a minimum shall address the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers compensation cases. Commenter indicates that for many of the treatment procedures and modalities in the chronic pain section, this minimum is not met. Commenter adds that treatment procedures are listed for treating chronic pain in conditions that are unlikely to be work-related. Commenter states Labor Code sections 4600(b) and	August 12, 2008	adapted from the Work Loss Data Institute's Official Disability Guidelines (ODG) satisfies the requirements of the statute that the Guidelines Adopted be "scientific and evidence-based, peer-reviewed, and nationally recognized" based on the 2005 RAND Report. (Lab. Code, §§ 77.5(a), 4604.5(b), and 5307.27; see, Table 4., p. 21; Table 4.2, p. 27.) Moreover, upon thorough review of the entire ODG pain chapter by the Division of Workers' Compensation (DWC), and the Medical Evidence Evaluation Advisory Committee (MEEAC), and designated subject matter experts, it was determined that the ODG pain chapter was appropriate to supplement the MTUS as recommended in the 2005 RAND Report (at pp. xxx, 86). Further, to insure that the requirements of the statutes were being met, DWC added topics to the chronic pain medical treatment guidelines which were not addressed by the ODG chapter on pain. To this end, Evidence-Based Reviews (EBRs) were conducted and recommendations were	

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	4604.5(a) provide that treatment in accordance with MTUS meets the requirement the employer provide treatment that is reasonably required to cure or relieve the effects of injury and the MTUS is presumed to be correct. Commenter indicates the legislature intended the MTUS to assure injured workers received quality, appropriate care and to minimize disputes concerning that care. Commenter states that ACIC's review suggests the chronic pain guidelines as drafted do not provide clear guidance for practitioners and utilization reviewers, contain internal inconsistencies, have not assessed the strength of evidence as required by the existing rules, are overly supportive of off-label use, and may do more to produce controversy than provide a standard. Commenter indicates rather than providing useful and evidence-based guidelines, the chronic pain guidelines are more like a smorgasbord of treatments from which a provider may select. Commenter states the guidelines contain discussions of "any evidence" rather than scientific and evidence-based approach with little or no reference to the strength of evidence standards. Commenter adds on the other hand, some treatments and modalities are not recommended, but the rejection is of evidence appears to be no worse than some of that for recommended treatment. Commenter states that if this is a misreading, it is because of a structure that doesn't allow ready evaluation of the strength of evidence.		included in the Chronic Pain Medical Treatment Guidelines. Moreover, EBRs were conducted in individual treatment topics which were determined by the ODG chapter on pain to be "under study." The ODG chapter on pain uses the term "under study" for some individual treatment topics. The term "under study" indicates that the evidence was reviewed but ODG was unable to make a recommendation either in support or against the treatment based on the insufficiency of the evidence. Because the MTUS is presumed to be correct on the issue of extent and scope of medical treatment (Lab. Code, § 4604.5(a)), and because of the lack of guidance in the ODG chapter on pain on these topics, it was necessary for the DWC to conduct EBRs on these individual treatment topics to determine whether or not the treatment should be recommended. Just because the evidence is not sufficient, this does not necessarily mean that the individual treatment topic should not have a recommendation. The EBR development process in this regard was designed to meet the requirements of the statutes. (See Appendix B—Chronic Pain Medical Treatment Guidelines-Evidence-Based Reviews, which is part of the rulemaking file.)	

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			Commenter is correct the legislature intended the MTUS to assure that injured workers receive quality, appropriate care, and to minimize disputes concerning medical treatment. We disagree, however, with the comment which suggests that the Chronic Pain Medical Treatment Guidelines as proposed do not provide clear guidance for practitioners and utilization reviewers. Besides being accepted by treating physicians, the ODG is also the default guideline for every major workers' compensation payor in the United States. (See, ODG's Jurisdictional Adoptions of Treatment Guidelines in North America With Contact Information and ODG's Guidelines Licensed by Top WC Payors, which have been added to the rulemaking file.) It is not clear what commenter means when he argues that the Chronic Pain Medical Treatment Guidelines contain internal inconsistencies as he does not provide examples. Commenter indicates that the Chronic Pain Medical Treatment Guidelines have not assessed the strength of evidence as required by the existing rules. Commenter is incorrect. The issue of the application of the strength of	

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			evidence is discussed in section 9792.25(c)(1) below. The comment that the guidelines are "overly supportive of off-label use" is misplaced. Off-label use of medication is a common medical practice and it affects treatment decisions. Moreover, throughout the guidelines this is supported by scientific evidence, either against its use or in support of its use, and commenter offers no evidence to the contrary. Finally, careful selection of treatments is important as chronic pain issues are diverse, hence a range of treatment options are necessary to treat the individual case, and the introduction is intended to present the overall philosophy and approach.	
9792.24.2 General Compliance with the Statutes-Lab. Code, §§ 4604.5(b), 5307.27	Commenter states in Labor Code section 5307.27 the Legislature specifically requires the administrative director to create a treatment schedule that incorporates "evidence-based, nationally recognized, peer reviewed standards of medical care." Commenter opines as the model treatment guideline to be used in the interim, the Legislature mandated the ACOEM guidelines. Commenter opines regarding which medical treatment guidelines to use, the Legislature already made the social policy decision – the Legislature chose the ACOEM guidelines. Commenter states unless there is an area that is left unaddressed by ACOEM, the administrative director should continue to rely on the ACOEM guidelines.	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Disagree.** See response to comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above. Moreover, commenter argues that the Legislature mandated the ACOEM guidelines as the model treatment guideline. Labor Code section 5307.27 provides that "… the administrative director, in consultation with the Commission on Health and Safety and Workers'	None.

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	Commenter states CWCI is aware ACOEM is circulating a comprehensive chronic pain management guideline for a pre-publication review by physicians and other interested parties. Commenter recommends the Administrative Director should wait for the conclusion of that review and the publication of the new guidelines both because the Legislature made the policy decision to rely on ACOEM and because these revised guidelines provide clear, definite recommendations that are supported by medical evidence that is graded in accordance with the Strength of Evidence Range contained in the regulations. Commenter recommends the Administrative Director postpone the revision of the medical treatment utilization schedule for chronic pain guidelines until the revised ACOEM chronic pain guidelines are reviewed and considered for adoption.		compensation, shall adopt a medical treatment utilization schedule..." The statute does not limit the administrative director to the use of the ACOEM Practice Guidelines or to simply augment the ACOEM Practice Guidelines. Commenter is correct, however, that the ACOEM Guidelines, were to be used on an interim basis (see, Lab. Code, §4604.5(c)), not on a permanent basis.	
9792.24.2 General/Wait to Review ACOEM Chronic Pain Chapter	Commenter indicates CWCI had the opportunity to review a pre-publication draft of ACOEM's revised chapter on Chronic Pain. Commenter finds the draft revised guidelines in that chapter to be comprehensive, based on the highest standards of Evidence Based Medicine and evaluated according to the rating criteria and strength of evidence standards in the regulations. CWCI believes ACOEM's draft guidelines are preferable to the proposed guidelines. Commenter states the Legislature determined that the standard of medical care in the workers' compensation system is evidence based medicine and chose the ACOEM Practice Guidelines initially as the epitome of Evidence Based Medicine in California. Commenter states that using a unified and consistent medical philosophy will provide California with a more consistent and predictable standard of care. Commenter recommends that the DWC restore the	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Disagree.** See response to comment submitted by Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, commencing with the second paragraph, above.	None.

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	existing Chronic Pain Guidelines into the topic sections and consider replacing it with ACOEM's update of Chapter 6 that addresses Chronic Pain in its Practice Guidelines. Commenter adds that if the DWC declines to adopt the ACOEM Practice Guidelines' revision of Chapter 6 on Chronic Pain and decides to instead adopt adapted ODG guidelines, CWCI recommends revising the proposed guidelines to address only chronic pain; specifying the frequency, duration, intensity, and appropriateness for each procedure; clearly stating in the guidelines the recommendation status ("Recommended," "No recommendation," or "Not Recommended") together with the strength of evidence for each service, and including in the regulations by reference, the appendix of evidence-based reviews with MTUS rating criteria for the studies.			
9792.24.2 General/Wait to Review ACOEM Chronic Pain Chapter	Commenter is concerned about the premature adoption of any treatment guideline for chronic pain. Commenter understands that ACOEM has distributed a draft of their comprehensive chronic pain guideline for pre-publication review by various stakeholders. Commenter states in light of the complicated treatment issues, State Fund, including their Medical Director, recommends that any treatment guideline for chronic pain is not promulgated until the community has had an opportunity to review the ACOEM pain management guideline and compare it to others.	Marie W. Wardell, Claims Operations Manager, State Compensation Fund, August 12, 2008	**Disagree.** See response to comment submitted by Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, commencing with the second paragraph, above.	None.
9792.24.2 General/Wait to Review ACOEM Chronic Pain Chapter	Commenter testified in response to what he believes were inaccuracies from stemming from the hearing in Southern California regarding these regulations. Commenter states an online newsletter covering workers compensation issues attributed comments to several of those who testified at the hearing which are flatly wrong and need to be corrected for the record. Commenter states because the speakers at the hearing misrepresented ACOEM's guidelines, he thinks it is very important DWC have the facts. Commenter	Steven C. Schumann, M.D., Legislative Chair, Western Occupational & Environmental Medicine Association, A Component Society of ACOEM,	**Disagree.** See response to comment submitted by Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, commencing with the second paragraph, above.	None.

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	states first, comments suggesting ACOEM's guidelines do not "reflect evidence-based studies" are simply wrong. Commenter states if anything, ACOEM's guidelines include MORE evidence from randomized clinical trials than other guidelines currently being used. Commenter adds to suggest ACOEM's evidence is "weaker," as one speaker put it, really bends reality. Commenter states ACOEM's rating system, which DWC adopted a year ago, demands the highest standards of evidence possible in the process of making recommendations. Commenter also wants to assure ACOEM has been very fair and accommodating to several of the organizations testified at the hearing in accepting their input on their guidelines. Commenter states ACOEM actually postponed the publishing process in order to give them extra time to comment last fall on their chronic pain guidelines. Commenter states they would be happy to share information about their peer review process, which is transparent and very inclusive. Commenter states the DWC is to be commended for its decision to expand the MTUS to include a more detailed approach to chronic pain. Commenter states chronic pain in today's workplace presents a challenge to the physicians caring for injured workers. Commenter states it should be noted reaching agreement on an evidence-based guideline for treatment of chronic pain is an exceedingly complex, difficult and often controversial effort. Commenter states while they applaud all DWC has done recently to build a strong guideline-based medical review system, and specifically for expanding the discussion of chronic pain, they do have some concerns about the details of the proposed changes to MTUS. Commenter states he will make some very general observations and his colleague Kurt Hegmann	August 12, 2008, Written and Oral Testimony		

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	will offer a much closer look at the issues at hand. Commenter states ACOEM has just completed the Chronic Pain Update to its comprehensive practice guidelines. Commenter states as they have completed all research, evidence evaluation, synthesis and peer review of the ACOEM Chronic Pain update, they are in a unique position to assess DWC's proposed treatment guideline. Commenter states after thorough review, they believe the Division's proposal would benefit from inclusion of added content from this update. Commenter states ACOEM's Chronic Pain panel members, trained in their evidence-based methodology, found shortcomings with the proposed treatment guideline they would like to share in order for DWC to make the most informed decisions going forward. Commenter states of particular note is what they believe to be a lack of specificity in treatment options and the potential for confusion among providers and payers could result from combining treatment recommendations authored by the Division and adapted from ODG. Commenter states combining recommendations in this way utilizes two completely different article-grading methods and methods to develop guidance, while presenting recommendations in two different formats on a given topic. Commenter believes it's worth taking a second look at this part of the proposal to ensure no inconsistency is introduced into the overall system. Commenter states in addition, the proposed Chronic Pain treatment guideline appears to be quite limited, potentially restricting services to injured workers. Commenter states Dr. Hegmann will discuss this in more detail, but he summarizes by saying he believes treatment options must include as much specificity as the evidence allows in order for guidelines to achieve their full potential in reducing harmful variations in			

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	care and reducing costs. Commenter proposes as a remedy, they encourage the Division to use portions of the ACOEM Chronic Pain Update to supplement or modify the proposed rule if necessary. He concludes by reiterating, beyond these specific issues, ACOEM is an enthusiastic supporter of California's efforts to shape an effective guideline system and would be pleased to offer any additional analysis, review or recommendations to improve the current proposal.			
9792.24.2 General/Wait to Review ACOEM Chronic Chapter	Commenter states earlier this year ACOEM completed their update for chronic pain and is currently in the process of completed this very detailed work. The ACOEM update was a culmination of thousands of hours of evidence review, of grading of articles, critiquing of articles, literature review and ultimately a robust debate by a multi-disciplinary panel of experts with representation from a cross section of specialties to cover the diverse needs of injured workers with chronic pain from primary care where most of them are seen through tertiary care. In comparing the proposal with findings of our recent review, commenter believes there are some issues including a few recommendations which may help. First, commenter believes although mistreating or under treating pain is a significant concern, another concern needs to be risk for patients and physicians from over treatment by physicians of the patients with chronic pain. Especially if they have potential for adverse effects. Even non-invasive treatments can result in irreparable harm to the patient's socio-economic status, home life personal relationships and quality of life.	Kurt Hegmann, Editor-in-Chief, ACOEM's Occupational Practice Guidelines, August 12, 2008, Oral Testimony	**Disagree.** See response to comment submitted by Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, commencing with the second paragraph, above.	None.

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	Evidence is gathering that the use of active treatment modalities including exercise, education and activity modifications should be emphasized over passive treatments such as medication, injections or physical modalities as they produce better clinical outcomes for patients and workers with chronic pain. As noted earlier, commenter is concerned with potential confusion for providers and payers introduced by a combination of treatment recommendations offered by the Division and adapted from ODG. Use of these two different methods provides for substantial confusion to the reader. Errors of confusion may include difficulties with understanding the evidence, inability to objectively test the recommendations for reproducibility and impairment of the ability to develop or subsequently revised guidance. The Division should be lauded for its use of one of these methods which appears to follow specific methodology resulting in more clear testable, reproduceable development of evidence. The other is unclear and appears generally untestable. As a general observation, the proposed rule appears to be limited. It lacks specificity in expressing recommendations. Commenter has some concern about the potential for restriction on access of care by injured workers. For example, in their update they have 221 recommendations they have come up with, which is more than are in the proposed rule. In order to help, ACOEM has given permission for the Division to use portions of its chronic pain update to help address some of these areas to supplement			

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	where it may be beneficial to do so. Commenter states the draft document is unclear. There are some recommendations that come up which do not seem to be particularly directly relevant to chronic pain. For example, acute pain is mentioned and post mastectomy patients are mentioned. Although chronic pain is now almost universally accepted as a biopsychosocial condition, there is little guidance to help the provider as far as how to adopt and implement it. The lack of treatment algorithms is also an area for potential improvement. Algorithms provide further guidance about the sequence of treatment and some providers very much like those algorithms, although admittedly some do not. Nevertheless, for those who like them, they do help to provide a quick accurate guidance for busy clinicians. Work hardening or work conditioning programs are not mentioned and yet commenter believes they are beneficial and they are established and often accredited. ACOEM has identified over 50 studies of the use of medications in the subacute or chronic pain periods that may be of assistance in the guidelines. The document appears to endorse the use of a specific widely used classic anti-depressants for treatment of chronic pain which is a selective serotonin reuptake inhibitors or SSRIs. There is evidence that these medications are effective for treatment of the non-occupational condition, fibromyalgia. However, all the other studies on typical occupational injuries such as spine pain and those sorts of things going back 15 years document that they are ineffective compared with placebo for treatment of these typical occupational conditions and yet the proposal appears to endorse these medications. Complex regional pain syndromes are infrequent but			

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	very painful and cause the disorder. The current document does little to help guide clinicians towards the treatments that evidence shows are more effective. For example, dysphosphonates appear to have the largest magnitude reductions in pain ratings. The text also states that studies on calcionate have "mixed results" and yet our careful review of the evidence indicates that the two higher qualities studies both had positive beneficial results as only the single lower quality study which is negative which suggests that these are in fact efficacious interventions. Arthritis is addressed in a fairly limited manner. There are over a hundred quality studies on dozens of treatments that appear to have been overlooked and thus aren't addressed. It is recommended that the diagnosis be deferred for comprehensive review. Quality evidence also documents adding corticosterioids to trigger point injections produces no added benefits while simultaneously potential exposing patients to an unnecessary adverse effect.			
9792.24.2 General/Do not Adopt Portions of ACOEM Chronic Pain Chapter	Commenter states that in their review of the most recent update to the ACOEM Low Back guidelines (2008), and subsequently regarding the updated ACOEM draft Chronic Pain chapter (2008 draft), they note and have expressed directly to ACOEM on several occasions their serious concern not only with their recommendations concerning SCS and IDDS, but their draconian approach to a wide array of proven tests, therapies and interventions used to treat injured workers suffering from pain-related injuries. Commenter indicates that his organization's concerns include: I. Extremely limited expert review of pain-related tests, therapies and interventions (and non-involvement of the medical societies considered expert in these areas); 2. Incomplete and	Eric Hauth, Executive Director, Neuromodulation Therapy Access Coalition, August 12, 2008	**Agree in part**. See response to comment submitted by Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, commencing with the second paragraph, above. **DWC does not agree** with comment analyzing substance of ACOEM's Chronic Pain chapter as DWC did not revise the chapter in connection with this rulemaking.	None.

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	outdated evidence (though citations now include many more articles, by your own admission you continue to disregard the substance of this additional evidence); 3. Inconsistencies in the application of ACOEM's evidence-ranking criteria; and 4. Elimination of approximately 50 percent of tests, therapies and interventions Commenter adds that it is his organization's understanding in discussions with our member medical professional societies that ACOEM's process failed to include experts in many of the areas they evaluated - a process that in the majority of tests, therapies and interventions cases evaluated in these guidelines yielded recommendations based primarily on the views of ACOEM's extremely limited author panel. Commenter indicates that for these reasons, his organization strongly support the DWC's proposed approach at Section 9792.23.5 to limit the use of ACOEM guidelines to the 2004 version of the ACOEM Practice Guidelines, 2nd Edition, Chapter 12 and to not rely on the most recent 2008 version of ACOEM Low Back chapter in the proposed DWC treatment guidelines for lower back injuries. Commenter also encourages the MEEAC committee in their ongoing Low Back chapter consideration to also avoid ACOEM's updated Low Back chapter and to choose alternative, fair and balanced guideline approaches such as those done by the State of Colorado, Delaware, Minnesota and Wisconsin. [Commenter encloses a "Joint Position Statement: Updated ACOEM Chronic Pain and Low Back Guidelines" for DWC's consideration.]			
9792.24.2 General/Do not Adopt Portions of ACOEM Chronic Pain Chapter	Commenter states that following the testimony at the hearing, he is compelled to follow up his written and oral testimony with a brief observation concerning the testimony provided by the two ACOEM representatives, as he understood it. Commenter	Stephen J. Cattolica, AdvoCal, August 7, 2008	**Agree in part.** See response to comment submitted by Eric Hauth, Executive Director, Neuromodulation Therapy Access Coalition, dated August 12, 2008,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	indicates that as he understood correctly, ACOEM requested that the Division review the latest ACOEM pain guidelines for the purpose of integrating the ACOEM pain guidelines into the ODG pain guidelines for the California MTUS. Commenter indicates that he construes this tactic as an indirect and off-handed way for ACOEM to claim that their pain guidelines were adopted in California. Commenter states that pared down to the basics, ACOEM requested that the Division compare the ODG recommendations with the ACOEM recommendations and consider where the two guidelines sets differed. Commenter adds that they requested that where both agreed, no change would be considered, where the two differed, the Division would consider and adopt the ACOEM recommendations over ODG. Commenter states that if this interpretation of their testimony is correct, the resulting guidelines would be virtually identical to the ACOEM pain guidelines, albeit through a back door tactic. Commenter states it is a classic "divide and conquer" plan. Commenter states that he cannot urge the Division strongly enough to reject this concept. Commenter states that notwithstanding the apparent intent as he stated it above, ACOEM has often argued in their own defense that to combine guidelines from different sources would confuse the community. Commenter indicates that the Division will recall this same argument has often been put forward by insurers, claims administrators and employers as a reason to adopt only the ACOEM guidelines for California. Commenter states that for ACOEM to now promote this idea is disingenuous and borders on the unethical. Commenter again, urges the Division to reject ACOEM's suggestion of a blended guideline in the manner they suggest.		above.	

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9792.24.2 General/Do not Adopt Portions of ACOEM Chronic Chapter	Commenter echoes and strongly supports Mr. Cattolica's comments in direct opposition to ACOEM's testimony this afternoon [at the public hearing]. I have been briefed by my staff in attendance and fully agree as does Medtronic.	N. William Fehrenbach, Director, State Government Affairs Medtronic August 10, 2008	**Agree in part.** See response to comment submitted by Eric Hauth, Executive Director, Neuromodulation Therapy Access Coalition, dated August 12, 2008, above.	None.
9792.24.2 General/Do not Adopt ACOEM Chronic Pain Chapter	Commenter understands that current California DWC guidelines rely primarily on the ACOEM Practice Guidelines, 2nd Edition, 2004. Commenter states that he has substantial concerns with the recent updates to the Low Back and Chronic Pain chapters. Commenter indicates that of particular concern are updated ACOEM recommendations against coverage of more than 50% of tests, treatments, and therapies considered standard practice in the medical community, including spinal cord stimulation and opiate medical therapy. Commenter states that it is evident from testimony given by ACOEM physician representatives at the DWC public hearing on August 12, 2008, that they disagree with concerns voiced at the previous day's hearing related to the ACOEM updated guideline process and outcomes. Commenter offers into the record a joint position statement (attached) in direct response to the updated ACOEM low back and chronic pain chapters drafted by the following societies: • American Academy of Pain Medicine (AAPM) • American Pain Foundation (APF) • American Society of Interventional Pain Physicians (ASIPP) • International Spine Intervention Society (ISIS) • National Pain Foundation (NPF) • Neuromodulation Therapy Access Coalition (NTAC)	John Hernandez, PhD Vice President, Health Economics and Reimbursement Boston Scientifics Neuromodulation August 12, 2008	**Agree in part.** See response to comment submitted by Eric Hauth, Executive Director, Neuromodulation Therapy Access Coalition, dated August 12, 2008, above. With regard to ACOEM's Revised Low Back Disorders (Chapter 12), issued December 1, 2007, DWC has not adopted that chapter. The chapter that is in effect is the Low Back Complaints chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 12).	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	• North American Neuromodulation Society (NANS) Commenter states that the position statement documents the opposition to the updated ACOEM guidelines by these prominent societies. Boston Scientific, in conjunction with these medical experts, does not believe it would be in the best interest of patients or the DWC to include ACOEM low back or chronic pain guidelines, even to supplement or enhance proposed guidelines.			
9792.24.2 General/ACOEM Low Back Pain Chapter	Commenter states that the ACOEM Practice Guidelines, 2nd Edition (2004), Charter 12 misrepresents contemporary medical scientific literature of low back pain secondary to mechanical injury. Commenter states that authoritative peer reviewed medical literature establishes that 16-30% of chronic low back pain resulting from injury is due to sacroiliac joint biomechanical dysfunction. Commenter indicates that ACOEM guidelines are absent algorithms for diagnosis of this type of work injury. Commenter opines that as a result of this oversight, the following has occurred within the workers' compensation medical system in California: 1. Tens of thousands of injured workers are misdiagnosed annually and never receive therapy specific to their injury; these errors occur despite the requirements that work injuries be "specifically diagnosed". 2. Primary Treating Physicians (P.T.P.'s) and Qualified Medical Examiners (Q.M.E.'s) have little incentive to become knowledgeable about chronic low back pain due to sacroiliac joint dysfunction and to incorporate this knowledge into their evaluations. 3. Many injured workers who have non-surgical chronic low back pain exit their workers' compensation evaluations, ratings, and settlements with incorrect diagnoses, ongoing suffering, and physical inability to ever re-enter the workplace.	Lawrence Badgley, M.D. Oral & Written August 12, 2008	**Disagree.** Chapter 12—Low Back Complaints chapter (ACOEM Practice Guidelines, 2nd Edition (2004) was adopted as part of the MTUS regulations when they became effective on June 15, 2007. The present proposed update of the MTUS regulations proposes to reorganize, in relevant part, the MTUS on a chapter by chapter basis and it is not intended to update chapter 12 on a substantive basis. Chapter 12 will be updated in the future, and commenter may, of course, resubmit his comments on the substance of the Low Back Complaints chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 12).	None.

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	Commenter states that these circumstances were they to occur in the private medical arena, would be called "medical malpractice". Commenter indicates that these circumstances, as extrapolated from his own examinations of hundreds of injured workers, each year costs the California workers' compensation medical system hundreds of millions of dollars that could have otherwise been saved and/or more appropriately expended. Commenter states that development of guidelines and algorithms for diagnosing work-related sacroiliac joint injury is not problematic. In early 2007, the O.D.G. set forth a set of criteria for diagnosing this specific work injury. Commenter states that he has used the O.D.G. criteria to encourage Utilization Reviewers to authorize care for tens of injured workers who would have otherwise been relegated (within ACOEM guidelines) to a status of disabled and "permanent and stationary"; all based upon incorrect diagnoses.			
9792.24.2 General/Acute Treatments/Lack of Cross-Reference	Commenter states that the Chronic Pain Medical Treatment Guidelines combine acute and chronic pain medical treatment discussions. Commenter states that in addition to mixing discussions of acute and chronic pain in the chapter, there are items discussed that have no relevance to treatment of chronic pain such as the discussion of power mobility devices found on page 64 of the chronic pain section. Using opioids as an example, there are discussions relevant to opioids found under different headings as is true for other treatments and modalities. Commenter states that at the very least, there should be cross references so providers and others do not have to search for all the pieces.	Keith Bateman, Vice President Property Casualty Insurers Association of America August 12, 2008	**Agree in part. Agree** with the comment that the Chronic Pain Medical Treatment Guidelines incorrectly combine discussions of acute and chronic pain. The acute treatments discussions should only appear in the clinical topics sections of the MTUS and should not be addressed in the Chronic Pain Medical Treatment Guidelines. Accordingly, the revised version of the Chronic Pain Medical Treatment Guidelines will be corrected by editing out all of the references to acute treatments. **Disagree** with comment stating	The revised version of the Chronic Pain Medical Treatment Guidelines will be corrected by editing out all of the references to acute treatments. Specific treatment guidelines that contain references to acute treatments will be edited to remove the specific language.

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			that power mobility has no relevance to the treatment of chronic pain. Power mobility may be relevant to the extent that assistance devices may be necessary in patients with chronic pain who demonstrate functional impairment caused by that pain. Commenter's suggestion of using cross references so providers and others do not have to search for all the pieces is a good suggestion. DWC applied to the reorganization of the transcutaneous electrotherapies. This however, is a laborious endeavor. DWC will continue to refine the guidelines throughout its rulemaking in the future, and commenter's suggestion will be taken into consideration in the future.	
9792.24.2 General/Acute Treatments	Commenter indicates despite the title "Chronic Pain Medical Treatment Guidelines," more than chronic pain is addressed in the guidelines (for example *Medications for acute pain (analgesics)*). Commenter states it is not always clear whether recommendations in the guidelines are for the treatment of chronic pain or for acute or subacute pain or for the treatment of a particular condition (for example *TENS, post operative pain (transcutaneous electrical nerve stimulation) [ODG], Testosterone replacement for hypogonadism (related to opioids)*). Commenter adds when the guidelines address services for conditions other than chronic pain that are covered by other sections of the MTUS, contradictions, confusion and disputes over competing presumptions will arise. Commenter opines this uncertainty, conflict and	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Agree in part.** See response to comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above.	See action taken in connection to comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above.

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	disputes can be diminished by identifying and removing non-chronic pain recommendations and references from the proposed guidelines, or avoided by remaining with the ACOEM practice guidelines which offer consistency across chapters.			
9792.24.2 General/Acute Treatments	Commenter submits Appendix 1 to his August 7, 2008 correspondence. In the appendix commenter adds what he indicates are instances of acute treatment recommendations in the MTUS chronic pain proposed Guideline. These instances are listed as appearing at p. 14 AEDs not recommended for acute pain, p. 15 Gabapentin use in acute pain, p. 40 manipulation for acute conditions, and p. 40 medications for acute pain (analgesics).	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part.** See response to comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above.	See action taken in connection to comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above.
9792.24.2 General/Acute Treatments	Commenter states that the Chronic Pain Medical Treatment Guidelines contain multiple determinations regarding Acute Pain. Commenter states that these need to be removed in order to prevent conflict between two guidelines, both of which are presumed to be correct. Commenter indicates that many topics speak directly to Acute Pain treatment while others speak of first line of treatment or diagnostic uses. Commenter states that there is a whole section on "Medications for Acute Pain" and "Opioids-Criteria for Use" followed by "Opiods for Chronic Pain." Commenter believes that it is critical to remove all allusions to Acute Pain treatment from this guideline in order to prevent conflicts with the Clinical Topic Sections where acute care is covered.	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Agree in part.** See response to comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above.	See action taken in connection to comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above.
9792.24.2 General/Lack of Algorithms	Commenter indicates the lack of treatment algorithms in the proposed guidelines is of concern. Commenter opines the algorithms provide further guidance about the sequence of treatment. Commenter states good algorithms include branches to offer guidance in cases with different progressions, circumstances, or outcomes. Commenter adds they also often include integration with time frames indicating when tests or treatments are appropriate in the course of a case.	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** Although not clear from the comment, it appears that commenter is referring to the clinical flow charts as found in ACOEM Practice Guidelines (2nd Edition). DWC notes that not all algorithms require depiction as a flow chart and a clinical sequence can also be represented in written	None.

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	Commenter indicates algorithms assist in the development of treatment plans and provide quick, accurate guidance for busy clinicians, who otherwise might use multiple guideline recommendations in no particular order, without a suggested preferential hierarchy for sequencing of treatments. Commenter opines the lack of preferential sequencing of treatment interventions may increase variance and duration of pain and disability.		or narrative form. The Merriam-Webster Dictionary defines the term algorithm, in relevant part as "a step-by-step procedure for solving a problem or accomplishing some end." The Chronic Pain Medical Treatment Guidelines do contain an algorithm as stated in the first paragraph of the Introduction at page 1. This algorithm is applied as follows: (1) In following the clinical topics section, the physician begins with an assessment of the presenting complaint. (a) If there is a red flag, for potentially serious condition, this would trigger an immediate intervention. (b) If there is no red flag, then conservative management is provided. (2) If the complaint persists, the physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary. (3) If the patient continues to have pain that persists beyond the anticipated time of healing, without plans for definitive	

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			treatment, such as surgical options, the chronic pain medical treatment guidelines apply. At this juncture, the various approaches to treating chronic pain are described. It is clear that chronic pain management cannot be easily broken down into a stepwise manner especially when management of psychosocial factors is critical in chronic pain management. To the extent that the introduction to the chronic pain medical treatment guidelines provides a framework, this narrative provides the algorithm and it is not necessary that it may be provided in a flow chart. In terms of trying to create an algorithm for the remainder of the chronic pain medical treatment guidelines, Part 1 of the guidelines further introduces different models for understanding pain. Rendering these different models into an algorithm would be difficult if not impossible, as the approaches described cannot easily be scripted into a step-by-step algorithm. In Part 2 of the Chronic Pain Medical Treatment Guidelines, step-by-step instructions (algorithms) are used in some of	

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			the treatment topics. For example, algorithmic criteria are specified for the epidural steroid injection guidelines, and implantable drug delivery systems guidelines.	
9792.24.2 General/Lack of Algorithms	Commenter continues to urge DWC to make more use of a W.H.O. like step-wise algorithm. Commenter indicates while the W.H.O. step-wise algorithm deals with cancer pain, it could serve as a model approach for treating chronic pain that would focus on starting with conservative approaches before moving to more powerful drugs and other costly or risky modalities.	Keith Bateman, Vice President Property Casualty Insurers Association of America August 12, 2008	**Disagree.** See response to comment submitted by Barry Eisenberg, Executive Director of ACOEM, dated August 7, 2008, above.	None.
9792.24.2 General/ Biopsychosocial	Commenter states although chronic pain is now almost universally accepted as a biopsychosocial condition, there is very little guidance useful to a provider in the draft guidelines. Commenter indicates that while the draft document notes pain has a psychological component in the introduction (DWC page 5), and out of date psychological assessments are mentioned in several places as being recommended, the biopsychosocial model is never very well addressed without mention of fear avoidance. Commenter indicates the draft does not address the multiple biopsychosocial concerns that occur with chronic pain, but rather notes that potential psychological concerns are recognized as occurring with chronic pain. Commenter states it does not provide any information about potential psychosocial concerns, such as fear of re-injury, poor pain coping strategies or includes them in any treatment recommendations. Commenter indicates there is a considerable literature on these issues, which could have provided actual guidance for the practitioner; but the proposed text does not review or address it.	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** The Chronic Pain Medical Treatment Guidelines emphasize the biopsychosocial model of pain in the Part 1 Introduction. It clearly states that "The biopsychosocial model of pain instead recognizes that pain is ultimately the result of the pathophysiology plus the psychological state, cultural background/belief system, and relationship/interactions with the environment (workplace, home, disability system, and health care providers)." A substantial portion of Part 1 Introduction is devoted to describing behavioral and psychological aspects of chronic pain. In Part 2, many pages of treatment guidelines are devoted to addressing psychological treatment of chronic pain and the main purpose of chronic pain programs is to address biopsychosocial	None.

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			issues.	
9792.24.2 General/Clarity	Commenter states the Legislature not only defined the elements of the treatment schedule, it also provided that the guidelines set forth in the schedule "shall be presumptively correct on the issue of extent and scope of medical treatment" (section 4604.5). Commenter adds that this statutory presumption provides additional legal authority and is intended to limit disputes over which course of care is medically appropriate. Commenter indicates that when disputes have to be resolved, the WCALJ should be able to rely on the clarity of the recommendations, the weight of the supporting medical evidence, and the Strength of Evidence Range within the MTUS. Commenter adds that similarly, when the WCAB is required to determine disputed medical care, the MTUS and the presumption will direct that decision to the extent the scientific evidence allows. Commenter opines that needless ambiguity in the treatment schedule serves no one. Commenter opines that a guideline with ungraded evidence, contradictory or incomplete recommendations, and recommendations that are internally inconsistent, does not facilitate the legislative goal of identifying the best medical care for injured workers. Commenter indicates that while the Statement of Reasons provides considerable rationale for the use of the proposed ODG guidelines, there is no comparison to any other guideline considered by the Division or reviewed by the Medical Evidence Evaluation Advisory Committee. Commenter states that the Division does not assert that there is any urgency in developing pain management treatment guidelines that might justify ignoring the ACOEM guidelines in this area. Commenter recommends that even if the Administrative Director ultimately rejects the ACOEM pain management guidelines, a comparison review is essential to the development of the	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** Commenter is correct that the MTUS is "presumed to be correct on the issue of extent and scope of medical treatment." (Lab. Code, §4604.5(a).) In resolving medical disputes, the workers' compensation administrative law judge (WCALJ) relies on the MTUS as presumptively correct. If the condition or injury is not addressed by the MTUS, then authorized treatment may be provided pursuant to other guidelines which meet the requirements of Section 9792.25(b). With regard to commenter's comments regarding the strength of evidence, see response to her comments regarding section 9792.25(c)(1), below.	None.

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	definition of reasonable and necessary medical care in California.			
9792.24.2 General/Clarity	Commenter states that the scope of the draft of the DWC Chronic Pain Medical Treatment Guidelines is unclear. Commenter observes that a careful reading of the document shows that it includes far too many clinical situations that are inconsistent with Part 1 of the proposal that they "…apply to patients who fail to recover from and continue to have persistent complaints without definitive treatment, such as surgical options." (Page 1, par 1). Commenter states that many of the recommendations are largely, or completely irrelevant to occupational chronic pain; e.g., acute pain [Appendix 1], post-mastectomy (DWC pages 12, 22), central pain (DWC pages 13, 14), post-stroke pain (DWC pages 12, 14, 17), most headache disorder (pages 19, 21, 53, 79, 80) and cervical dystonia/torticollosis (DWC page 21).	ACOEM Barry Eisenberg, Executive Director, August 7, 2008	**Agree in part**. **Agree** that acute pain is outside the scope of the Chronic Pain Medical Treatment Guidelines. See response in connection with comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above. **Disagree** with the comment stating that many of the recommendations in the DWC Chronic Pain Medical Treatment Guidelines are largely, or completely irrelevant to occupational chronic pain. In terms of the scope of the pain guidelines, ODG reviewed the available evidence and often the scientific evidence based on studies of pain treatments for non-occupational conditions as there are few studies that are based exclusively on occupational conditions. Additionally, the pain mechanisms involved in occupational injuries are the same as they are for other non-occupational painful conditions. Whether the pain arises occupationally or not, the mechanism for the pain may be the same. Therefore, it is appropriate to include literature reviews from the available sources. For example, diabetic neuropathy pain or post-	See action taken in connection with comment submitted by Keith Bateman, Vice President, Property Casualty Insurers Association of America, dated August 12, 2008, above.

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			herpetic neuralgia pain is often used to test treatments for neuropathic pain and serves as a model to treat other forms of neuropathic pain. Post mastectomy pain is also considered a chronic neuropathic pain. With regard to the work-relatedness issue, this is more a medical-legal finding than it is a medical treatment issue.	
9792.24.2 General/Work Relatedness	Commenter states that the proposed Chronic Pain Medical Treatment Guidelines regulations discuss fibromyalgia, osteoarthritis, post-herpetic neuralgia, diabetic polyneuropathy, multiple sclerosis, breast cancer and other diseases for which there is no evidence of work relatedness. Commenter states that this implies that treatments effective for these entities should be effective for musculoskeletal pain. Commenter indicates that there is no scientific evidence to support that such conditions are work related. Commenter further states that users [of the guidelines] may assume that these entities are work related because they are discussed in a workers' compensation guideline. Commenter strongly suggests that these discussions be deleted from the guideline.	Jeffrey S. Harris, M.D., August 11, 2008	**Disagree.** See response, second paragraph regarding occupational chronic pain, to comment submitted by Barry Eisenberg, Executive Director, ACOEM, dated August 7, 2008, above.	None.
9792.24.2 General/Diagnostic Criteria	Under the subtitle entitled *Diagnostic Criteria,* commenter submits comments which relate to the Introduction of the Chronic Pain Medical Treatment Guidelines. Commenter states that in contrast to most of the other guidelines adopted by the DWC, the proposed chronic pain guideline does not include criteria for accurate diagnosis of the conditions discussed. Commenter states that this presents a significant problem for two reasons: treatment recommendations are made for specific diagnoses,	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** In Appendix A-Chronic Pain Medical Treatment Guidelines to the Initial Statement of Reasons (Appendix A to the ISOR) at page 7, DWC explained why the proposed Chronic Pain Medical Treatment Guidelines do not include criteria for accurate diagnosis of the conditions discussed. Under a section	None.

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	and the rate of erroneous diagnosis revealed in workers' compensation file audits and utilization review requests is quite high. Commenter opines that it is likely that treatment recommendations could be misapplied. Commenter suggests that the MEEAC or the DWC include diagnostic criteria in any pain guideline adopted. Commenter indicates while there are discussions [in the Introduction] of neuropathic v. nocioceptive pain, there are no clinical criteria to diagnose these entities. Commenter states that he was unable to find ICD-9 codes for either. Commenter further indicates that clinicians are required to assign generally accepted diagnoses to health problems for reimbursement and to locate best evidence for treatment. Commenter adds that statements such as "recommended as the standard of care for treatment of moderate or severe nocioceptive pain" (p 51) are less than helpful when there are no diagnostic criteria. Commenter indicates that this sentence goes on to state that the most common example of nocioceptive pain is cancer, which is at this time rarely work-related. Commenter continues to states that however, there are suggestions elsewhere in the guideline that low back pain can be nocioceptive, and in the paragraph following the above, the proposed guideline states "[c]hronic pain can have a mixed physiologic etiology of both neuropathic and nocioceptive components." Commenter states that there is no reference for this statement. Commenter adds that it is not helpful in the absence of diagnostic criteria. Commenter indicates that this discussion is particularly important for "neuropathic pain." Commenter states that some treatment modalities that have been studied are for conditions such as post-herpetic neuralgia and diabetic neuropathy, in which there is clear nerve damage. Commenter states that the guideline appears to imply that other chronic pain		subtitled, <u>ODG individual treatment topics not included in the chronic pain medical treatment guidelines as they are informative and/or educational in nature,</u> Appendix A states: "The ODG chapter on pain contains various individual treatment topics that are informative and/or educational in nature. Although informative, these concepts are not treatment topics and do not substantively add to the overall utility of the chronic pain medical treatment guidelines. Moreover, these concepts/definitions are either discussed in part in the introduction of the chronic pain medical treatment guidelines or were determined not to serve a purpose in the guidelines and the MTUS. Further, because the chronic pain medical treatment guidelines are primarily used to assist in the provision of medical treatment by offering an analytical framework for the evaluation and treatment of injured workers, and to help understand what treatment has been proven effective, DWC determined that streamlined guidelines would better serve the public. Accordingly, the ODG chapter on pain individual treatment topics not included in the chronic pain medical treatment	

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	conditions such as low back pain or upper extremity pain represent neuropathic pain, although the pathology of such conditions is in fact unknown. Commenter indicates that it is an unsupported extrapolation to suggest that modalities that are effective for diabetic neuropathy or post herpetic neuralgia, for example, should be effective for chronic musculoskeletal pain of unclear etiology. Commenter adds that the Ontario Task Force and the recent ACP/APS expert panel, which included distinguished researchers from relevant disciplines, specifically noted that attempts to extrapolate from one disease entity to another was not a tenable proposition: Diagnostic criteria are especially important for Chronic Regional Pain Syndrome (CRPS).[7 Chou R, Huffman LH. *Guideline for the Management of Low Back Pain in Primary Care*. Philadelphia: ACP, 2007; 8 Smith B. *Chronic Pain Initiative: Report of the Chair of the Chronic Pain Panels.* Toronto: Ontario Workplace Safety and Insurance Board, 2000.] Commenter states that an unexpectedly high number of cases of this relatively unusual and somewhat controversial complication are diagnosed in California. Commenter adds that records review often does not support the diagnosis. Commenter further adds that multiple unsuccessful treatments often follow. Commenter states that one must be able to determine whether the worker in fact has CRPS in able to determine whether a treatment is appropriate.		guidelines are as follows: Comorbid psychiatric disorders, CRPS (complex regional pain syndrome), CRPS, diagnostic criteria, Diabetic neuropathy, Diagnostic criteria for CRPS, Fibromyalgia syndrome (FMS), Myofascial pain, Number needed to treat (NNT), RSD (reflex sympathetic dystrophy), Substance abuse (tolerance, dependence, addiction), Sympathetically independent pain (SIP), and Sympathetically maintained pain (SMP)." (At p. 7.) Moreover, careful analysis was provided before determining whether to use ODG for Diagnostic Criteria. For example, if one were to use ODG for diagnostic criteria for CRPS, they present several different sets of criteria to choose from. There is controversy and there is not one standard set of criteria. Furthermore, additional research is ongoing to further validate what defines specific pain diagnoses. Under the Labor Code, the diagnosis is made by the treating physician, and the treatment is provided under the MTUS which is presumed correct under the statute. Thus, it is important that DWC carefully examine guidelines that are adapted and incorporated into	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			the MTUS as to avoid any interference with the presumption of correctness. Further DWC **disagrees** with the comment that there are no clinical criteria to diagnose neuropathic v. nocioceptive pain. In terms of the distinction between nociceptive and neuropathic pain, it is through a clinical assessment that the physician diagnosis what type of pain the patient is suffering. Part 1 of the Introduction states Neuropathic pain is characterized by lancinating, paroxysmal, tingling, and burning sensations that are distinct from nociceptive pain, and it is these features that distinguish nerve pain (neuropathic pain) from tissue injury pain (nociceptive pain).	
9792.24.2 General/Diagnostic tests	Commenter states that indications for many diagnostic tests are absent, although they are presented in other areas of the MTUS. Commenter further states that imaging and electrodiagnistic testing were shown to be far above the levels recommended per case. Commenter indicates that clear criteria are needed to ensure high quality care. Commenter adds that utilization review organizations receive a significant volume of requests for imaging, electro-diagnostic tests as well as diagnostic blocks, for chronic pain patients. Commenter states that evidence-based guidance is clearly needed to assure the best outcome for workers and cost effective utilization for the system as a whole.	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** In Appendix A-Chronic Pain Medical Treatment Guidelines to the Initial Statement of Reasons (Appendix A to the ISOR) at pages 6-7, DWC explained why the proposed Chronic Pain Medical Treatment Guidelines do not include certain diagnostic tests. Under a section subtitled, <u>ODG sections on diagnostic tests not included in the chronic pain medical treatment guidelines because they have broader uses beyond chronic pain medical treatment,</u> Appendix A states:	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			"The following individual treatment topics contained in ODG chapter on pain were omitted from the chronic pain medical treatment guidelines because they represent diagnostic tests that are not exclusive to the diagnosis of chronic pain. Because these tests have application beyond chronic pain diagnosis, they were omitted from the chronic pain medical treatment guidelines as inclusion would cause the chronic pain medical treatment guidelines to override the clinical topics guidelines. This in turn would limit the use of these tests which is not the intention of the chronic pain medical treatment guidelines. Omitting these diagnostic tests from the chronic pain medical treatment guidelines will allow application of the clinical topics guidelines of the MTUS. Further, it is beyond the scope of the chronic pain medical treatment guidelines to detail how these tests are used. The following is a list of the omitted individual treatment topics: Autonomic test battery, Current perception threshold (CPT) testing, Electrodiagnostic testing (EMG/NCS), Evoked potential studies, Neurometer®, Quantitative sensory threshold (QST) testing, Sensory nerve conduction threshold (sNCT)	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			device, Stress infrared telethermography, and Thermography (infrared stress thermography)." Thus, in order to avoid internal conflict in the MTUS, these tests were omitted from the Chronic Pain Medical Treatment Guidelines. This allows for these tests to be used/applied beyond chronic pain diagnosis, and to avoid preclusion from use in the clinical topics guidelines.	
9792.24.2 General/ Utility	Commenter states that the MTUS is a tool for all Workers' Compensation System Participants. Commenter opines that the proposed chronic pain guidelines appear to have been created by treating physicians for the exclusive use of treating physicians. Commenter states that if it were true that the MTUS was to be used exclusively by treating physicians, then the proposed pain management guidelines might be adequate, but that is not the case. Commenter adds that the Legislature requires that injured workers and physicians who treat them, attorneys, claims administrators, employers, and judges have a treatment schedule that is as straightforward as modern medical science permits. Commenter believes that the proposed revisions, based on the ODG guidelines will compromise the standard of care set by the existing MTUS. Commenter opines that the ACOEM chronic pain management guidelines will better serve the workers' compensation system. Commenter indicates that the Legislature enacted Labor Code section 5307.27 to create a tool for all workers' compensation system participants seeking to identify the best medical care for injured workers. Commenter states that the statute makes it clear that treatment guidelines are intended to be used by treating physicians, injured workers, utilization review	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** Commenter is correct that the MTUS is a tool for all workers' compensation system participants. We disagree, however, with the comment which suggests that the Chronic Pain Medical Treatment Guidelines appear to have been created by treating physicians for the exclusive use of treating physicians. As previously indicated, besides being accepted by treating physicians, the ODG is also the default guideline for every major workers' compensation payor in the United States. (See, ODG's Jurisdictional Adoptions of Treatment Guidelines in North America With Contact Information and ODG's Guidelines Licensed by Top WC Payors, which have been added to the rulemaking file.) Further **disagree** with the comment that the ACOEM chronic pain management guidelines will better	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	physicians, claims administrators, applicants' attorneys, defense attorneys, Workers' Compensation Judges, and the appeals board. Commenter states that section 4610 charges utilization review physicians with the obligation to determine the appropriateness of requested treatment within very tight time frames. Commenter states that treatment guidelines that provide clear direction, are well supported by scientific medical evidence, and are based on graded peer reviews are essential for the utilization review system to function as intended. Commenter states that conversely, a treatment schedule that makes conditional recommendations and offers no graded, scientific evidence is useless to that process.		serve the workers' compensation system for the reasons set forth in the response to comment submitted by Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, commencing with the second paragraph, above.	
9792.24.2 General/Utility	Commenter states that the draft provides a summary of different treatment options with an inconsistent amount of supporting detail. Commenter believes the document utilizes both open and proprietary evidence rating systems, which are quite different (e.g. DWC page 1), one of which appears at best difficult to reproduce. Commenter indicates while some of the summarizations of different treatments may be of interest, the draft does very little to help the practitioner to identify clear treatment options that may or may not make meaningful changes in the patient with chronic pain. Commenter states that instead, this is simply a summarization of particular treatments identified as being helpful.	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** See response to General/Utility comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, above.	None.
9792.24.2 General/Utility Style	Commenter states that many of the recommendations in the ODG material are labeled as generally "recommended" at the topic header. Commenter states that this is often misleading as the more specific text later narrows the indications for various therapies. Commenter states that there are a number of inappropriate statements in the text. Commenter indicates that some of it is hard to read. Commenter opines that the ODG material would benefit from a thorough review by a text editor. Commenter opines	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** See response to General/Utility comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, above. Further, **disagree** with the remaining comment. ODG's placement of "recommended" or	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	that a particularly difficult example of this is the opioid section, which is more than 15 pages long and quite redundant.		"not recommended" at the beginning of a section is a decision regarding their writing style. With regard to commenter's example, and given the complexity of certain treatment topics such as opioids, the length of the text is appropriate. Commenter does not address the substance and quality of that section.	
9792.24.2 General/Treatment Indications	Commenter submits comments under the subtitle, *Treatment Indications*. This comment addresses directly the development of "medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). Commenter states the MTUS methodology calls for indications, diagnoses, prior conservative treatments and contraindications as well as frequency and duration for treatment recommendations. Commenter, however, adds indications are sometimes absent and sometimes embedded in the text in a non-obvious manner in many recommendations. Commenter states indications should follow from diagnoses. Commenter indicates there are no diagnostic criteria for chronic pain except duration beyond expected time frames and the theoretical distinction between nocioceptive and neuropathic pain. Commenter adds the extensive but unfortunately non-specific and redundant opioid section (pp. 46-62) provides examples.	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** Although commenter submits his comments under the subtitle, *Treatment Indications*, his comments address three issues. Commenter first argues that there are no diagnostic criteria for chronic pain except duration beyond expected time frames and the theoretical distinction between nocioceptive and neuropathic pain. Commenter's comment has been addressed already in the response submitted in connection with his General/Diagnostic Criteria comment above. Commenter's remaining two issues are that indications are sometimes absent and sometimes embedded in the text in a non-obvious manner, and that the extensive but unfortunately non-specific and redundant opioid section (pp. 46-62) provides examples of this. DWC **Disagrees** with both comments. These comments were also addressed in DWC's response	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			in connection with commenter's General/Utility/Style comment, above.	
9792.24.2 General/Frequency, Duration & Intensity	Commenter notes that this section proposes to add a modified version of the ODG for Chronic Pain to the Medical Treatment Utilization Schedule. Commenter states that his organization must oppose this regulation as it stands. Commenter indicates that while the proposed material is a fine overview of a myriad of issues and treatment modalities concerning chronic pain, and can perform well as an educational tool, he does not see it functioning adequately as a treatment guideline. Commenter states that it does not meet the criteria found in Labor Code Sec. 5307.27 which states that the Medical Treatment Utilization Schedule "... shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases." Commenter indicates that the ODG gives an appropriateness rating of Recommended, Under Study, or Not Recommended but rarely provides recommended/allowable frequency, duration, or intensity indications.	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** The ODG guidelines are used extensively by many states and internationally as treatment guidelines. (See, ODG's Jurisdictional Adoptions of Treatment Guidelines in North America With Contact Information and ODG's Guidelines Licensed by Top WC Payors.) DWC's adaption preserves the functionality of the ODG Guidelines. Moreover, commenter does not specify the areas in which ODG fails to meet the requirements of the statute as set forth in Labor Code section 5307.27. Without specifics, DWC is unable to address commenter's comments in a more specific manner.	None.
9792.24.2 General/Functional Improvement	Commenter states that the chronic pain section pays lip-service to the importance of assessing functionality in evaluating the efficacy of treatments and modalities. Commenter states that more specific direction needs to be incorporated. Commenter indicates that in their September 2007 comments, ACIC suggested that the DWC develop a standardized form for monitoring physical functioning that physicians complete after each visit or every other visit. Commenter states that the Colorado has such a form, but its use may be limited to those being treated with opioids.	Keith Bateman, Vice President Property Casualty Insurers Association of America August 12, 2008	**Disagree**. DWC is in the process of developing a Functional Improvement Report form which will be part of a primary treating physician formal rulemaking. Commenter may re-submit his comments as part of that formal rulemaking.	None.
9792.24.2 General/ Critical	Commenter states that chronic pain has a genetic basis which continues to be ignored despite the vast amount	Edward Manougian, M.D.	**Disagree.** Comment is non-responsive.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Comments	of research and consequential literature. Commenter further states that a simple Google search using the words "c-fos pain" will open doors.	June 30, 2007		
9792.24.2 General/ Critical Comments	Commenter states that the DWC's proposed chronic pain medical treatment guideline appears to be lacking upon comparison. Commenter states that ACOEM has worked diligently to expand the breadth and specificity of its guidelines in recent years and in Chronic Pain especially. Commenter firmly believes that treatment option recommendations must include as much specificity as the evidence allows in order for evidence-based guidelines to achieve its full potential as a resource for the worker's compensation system, e.g., reduction in harmful variation in care, faster return to health, and lowered costs. Commenter adds that the ACOEM Chronic Pain update may be a useful resource to the Division going forward. Commenter sets forth a comparison of ACOEM and the DWC chronic pain medical treatment guidelines as follows: Treatment Recommendations: ACOEM Update: 221 MTUS Proposal: 113 (78 from ODG, 35 from DWC). References: ACOEM Update: 1557 MTUS Proposal: 366 Randomized Control Trials: ACOEM Update: 546 MTUS Proposal: 72	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** See response to comment submitted by Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, commencing with the second paragraph, above.	None.
9792.24.2 General/Specificity	Commenter states that the proposed DWC Chronic Pain Medical Treatment Guidelines lack specificity in expressing recommendations. Commenter states that there is a high degree of variability in explanatory detail. Commenter further adds that there is frequently contradictory and confusing text that would result in inconsistent interpretation at the provider	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** The MTUS update provides guidelines where there were none or insufficient guidelines before and therefore improves access to high quality health care. Waiting for the ACOEM revision would have	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	level, difficulty in assessing appropriateness of care and the risk of restricting high quality health care to injured California workers.		delayed access to this care. The 2005 RAND Report identified chronic pain as a priority issue which needed to be addressed in the MTUS. Completing the formal rulemaking will address this issue. Moreover, commenter does not offer substantive examples of what he means when he states that the uidelines lack specificity. He appears to argue that DWC's Guidelines risk restricting care although he does not state specifically where the ODG/DWC's Guidelines restrict care where the ACOEM Guidelines would allow it.	
9792.24.2 Comparison to ACOEM Chapter	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the heading Type of Guideline and subheading Peer-reviewed, commenter states that the DWC Chronic Pain Medical Treatment Guidelines is probably peer-reviewed. Commenter states that he is unsure because neither DWC nor ODG has published a methodology in a peer-reviewed journal. Commenter states that the ACOEM Chronic Pain Update is peer reviewed.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, publishing of the methodology in a peer reviewed journal is neither required by the Labor Code nor by the MTUS regulations.	None.
9792.24.2 Comparison to ACOEM Chapter/ Consensus Issue	Under the heading Type of Guideline and subheading Evidence-based, commenter states that he is unsure whether Part I of the DWC Chronic Pain Medical Treatment Guidelines is evidence-based because he is unsure as to whether a complete search of the literature was done. Commenter opines that Part 2 of the DWC Chronic Pain Medical Treatment Guidelines is not evidence-based because the guideline began with an evidence-based guideline and evolved into a	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Part I. Introduction to the Chronic Pain Medical Treatment Guidelines is introductory material for educational purposes. It provides a scientific foundation and background to the actual treatment recommendations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	consensus-based guideline. Commenter also adds that a complete search of the literature was not done. Commenter states that the ACOEM Chronic Pain Update is evidenced based.		Part 2. Pain Interventions and Treatments is based on the ODG, which has been determined to be evidence-based, except in those cases where the DWC has needed to perform evidence-based reviews (EBR). When the scientific literature showed inconclusive evidence to determine a recommendation, then consensus clinical advice was sought as good guidelines depend on both review of the scientific evidence and clinical expertise. **Disagree** with respect to the consensus issue based on the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, "[e]vidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased	

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			expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidate previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer." "Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming [tyrannized] by evidence, for even excellent external evidence may be inapplicable to or inappropriate for	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients." (See, Evidence based medicine: What it is and What it isn't, David L. Sackett, William M. C. Rosenberg, J. A. Muir Gray, R. Brian Haynes, W. Scott Richardson BMJ 1996;312:71-72 (13 January) http://www.bmj.com/cgi/content/full/312/7023/71). Moreover, consensus is not "evidence" in the scientific sense, but rather opinion based on the systematic review of the evidence. Although the specific term of "consensus" is not used in the guidelines, it is built into the evaluating process because it entails agreement among experts about the ratings and strength of recommendations. In his article entitled: *Evidence Based Medicine: What it is and What it isn't*, http://www.bmj.com/cgi/content/full/312/7023/71, Sackett states: "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			the best available external clinical evidence from systematic research." Thus, as applicable to guideline development, the evaluating committee reviews the medical literature and issues recommendations which, in some instances, involve the agreement among the reviewing experts about the ratings and strength of recommendations. This process is what guides the consensus element in a guideline. (See also, ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM's Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*, page 1.) Furthermore, DWC stated the following on the subject of consensus at page 45 of the ISOR: "[E]vidence-based medicine includes making recommendations even when there is insufficient evidence. "Guidelines [are] built on synthesis of the evidence, but go one step further to provide formal conclusions or recommendations about appropriate and necessary care for specific types of patients." (Crossing the Quality Chasm: A New Health System for the 21st Century/Committee on Quality of Health Care in America, Institute	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			of Medicine, National Academy Press, Washington, D.C., Fifth Printing, June 2004, p. 151.) Therefore, the first step of developing a clinical practice guideline is to do the evidence-based reviews. The second step involves "…reli[ance] on expert panels to arrive at specific clinical conclusions. Judgment must be exercised in this process because the evidence base is sometimes weak or conflicting, or lacking in the specificity needed to develop recommendations useful for making decisions about individual patients in particular settings (Lohr et al., 1998)." Crossing the Quality Chasm, Institute of Medicine, (2001), p. 151. Thus, the evidence-based review process includes an element of consensus when it is recognized that no good evidence exists. Commenter is correct that ACOEM's published evidence based process includes a consensus based approach when there is no evidence in the scientific literature.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Type of Guideline and subheading Nationally-recognized, commenter opines that the DWC Chronic Pain Medical Treatment Guidelines is not nationally-recognized. Commenter states that guidelines will not be recognized or used outside California. Commenter adds that guidelines will not be used as a text or reference because it is superficial	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, in the Initial Statement	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	and lacks scientific creditability. Commenter opines that the guidelines will only be used as evidence before the Workers' Compensation Appeals Board. Commenter opines that the guidelines are not even comprehensive or clear enough to be used in utilization review. He believes the guidelines are too superficial to be a reference text. Commenter states that the ACOEM Chronic Pain Update is nationally-recognized and internationally recognized. Commenter adds that the ACOEM Chronic Pain Update will be used as a text and reference throughout the English-speaking world.		of Reasons, DWC indicated that the 2005 RAND Report identified the Work Loss Data Institute's Official Disability Guidelines (ODG) as meeting the requirements of the statute that the guidelines adopted be "Scientific and Evidence-Based, Peer-Reviewed, and Nationally Recognized." (See, Table 4, p. 21; Table 4.2, p. 27.) DWC also previously noted that besides being accepted by treating physicians, the ODG guidelines are also the default guidelines for every major workers' compensation payor in the United States. (See, ODG's Jurisdictional Adoptions of Treatment Guidelines in North America With Contact Information and ODG's Guidelines Licensed by Top WC Payors.) Thus, the comment that the ODG guidelines as adapted are not nationally-recognized is not correct. However, in order to insure that there is strict compliance with the requirements of the California Labor Code, the DWC needed to go one step further. In that regard, the DWC carefully reviewed with the assistance of the MEEAC the ODG chapter on chronic pain and applied the requirements of then section 9792.23 (now proposed section 9792.26) and adapted this chapter to be used in the California workers' compensation system.	

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			The MTUS regulations are applicable to the State of California, and are not expected to be applicable to other states or to be used as a reference text.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter/Consensus	Under the heading Type of Guideline and subheading Consensus input, commenter opines that the consensus input in the DWC Chronic Pain Medical Treatment Guidelines is high. Commenter notes that the guidelines use consensus conference literature and non-peer reviewed articles. Commenter states that the ACOEM Chronic Pain Update contains low consensus input.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer." "Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming [tyrannized] by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients." (See, Evidence based medicine: What it is and What it isn't, David L. Sackett, William M. C. Rosenberg, J. A. Muir Gray, R. Brian Haynes, W. Scott Richardson BMJ 1996;312:71-72 (13 January)	

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			http://www.bmj.com/cgi/content/full/312/7023/71). Moreover, consensus is not "evidence" in the scientific sense, but rather opinion based on the systematic review of the evidence. Although the specific term of "consensus" is not used in the guidelines, it is built into the evaluating process because it entails agreement among experts about the ratings and strength of recommendations. In his article entitled: *Evidence Based Medicine: What it is and What it isn't*, http://www.bmj.com/cgi/content/full/312/7023/71, Sackett states: "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research." Thus, as applicable to guideline development, the evaluating committee, reviews the medical literature and issues recommendations which in some instances involve the agreement among the reviewing experts about the ratings and strength of recommendations. This process is what guides the consensus element	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			in a guideline. (See also, ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM's Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*, page 1.) Furthermore, in DWC stated the following on the subject of consensus at page 45 of the ISOR: "[E]vidence-based medicine includes making recommendations even when there is insufficient evidence. "Guidelines built on synthesis of the evidence, but go one step further to provide formal conclusions or recommendations about appropriate and necessary care for specific types of patients." (Crossing the Quality Chasm: A New Health System for the 21st Century/Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, D.C., Fifth Printing, June 2004, p. 151.) Therefore, the first step of developing a clinical practice guideline is to do the evidence-based reviews. The second step involves "…reli[ance] on expert panels to arrive at specific clinical conclusions. Judgment must be exercised in this process because	

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			the evidence base is sometimes weak or conflicting, or lacking in the specificity needed to develop recommendations useful for making decisions about individual patients in particular settings (Lohr, et al., 1998)." Crossing the Quality Chasm, Institute of Medicine, (2001), p. 151." Thus, the evidence-based review process includes an element of consensus when it is recognized that no good evidence exists. Commenter is correct that ACOEM's published evidence based process includes a consensus based approach when there is no evidence in the scientific literature.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Type of Guideline and subheading Political input into the composition of the committee and contents of Guidelines, commenter indicates that the DWC Chronic Pain Medical Treatment Guidelines has high political input into the composition of the committee and contents of Guidelines as opposed to the ACOEM Chronic Pain Update which is none.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Further, the comment does not address the substance of the rulemaking. The composition and purpose of the Medical Evidence Evaluation Advisory Committee is pursuant to section 9792.26 (formerly 9792.23), which was adopted through formal rulemaking effective June 15, 2007.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain	Under the heading Methodology and subheading Published Methodology, commenter indicates that the DWC Chronic Pain Medical Treatment Guidelines are not published as opposed to the ACOEM Chronic	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chapter	Pain Update which is published.		dated August 11, 2008, above. Moreover, the Work Loss Data Institute does publish ODG Methodology as contained in Appendix B, ODG Treatment in Workers' Comp Methodology Description using the AGREE Instrument (http://www.odg-twc.com/odgtwc/ODG_AGREE.htm). For further discussion of this subject, see response to comment on the issue of section 9792.20(e) Evidence-based concept, submitted by Steven C. Schumann, M.D., Legislative Chair, Western Occupational & Environmental Medicine Association, A Component Society of ACOEM, dated August 12, 2008, above. Moreover, with regard to the DWC Guidelines, the methodology applied is the MTUS methodology as contained in section 9792.25(c)(1), and explained in Appendix B, which is part of the rulemaking file.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Methodology for grading data objectively, commenter opines that the DWC Chronic Pain Medical Treatment Guidelines does not have a methodology for grading data objectively as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the Work Loss Data Institute does publish ODG Methodology as contained in Appendix B, ODG Treatment in Workers' Comp Methodology Description using the AGREE	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Instrument (http://www.odg-twc.com/odgtwc/ODG_AGREE.htm). For further discussion of this subject, see response to comment on the issue of section 9792.20(e) Evidence-based concept, submitted by Steven C. Schumann, M.D., Legislative Chair, Western Occupational & Environmental Medicine Association, A Component Society of ACOEM, dated August 12, 2008, above. Moreover, with regard to the DWC Guidelines, the methodology applied is the MTUS methodology as contained in section 9792.25(c)(1), and explained in Appendix B, which is part of the rulemaking file.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Consulting professional methodologist, commenter opines that the DWC did not consult a professional methodologist in developing its Chronic Pain Medical Treatment Guidelines as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, it is noted that in crafting its chronic pain medical treatment guidelines, the DWC relied upon the source organization (i.e, the Work Loss Data Institute and its Official Disability Guidelines) to provide the infrastructure to carry out the methodology. In crafting DWC's supplemental guidelines the DWC relied upon MEEAC, the subject matter experts members of MEEAC, and staff researchers who have the proper skills set to ensure	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			that proper methods were followed in the evidence-based review utilizing the strength of evidence methodology originally adopted from ACOEM, as contained in section 9792.25(c)(1). Moreover, the Work Loss Data Institute does publish ODG Methodology as contained in Appendix B, ODG Treatment in Workers' Comp Methodology Description using the AGREE Instrument (http://www.odg-twc.com/odgtwc/ODG_AGREE.htm). For further discussion of this subject, see response to comment on the issue of section 9792.20(e) Evidence-based concept, submitted by Steven C. Schumann, M.D., Legislative Chair, Western Occupational & Environmental Medicine Association, A Component Society of ACOEM, dated August 12, 2008, above. Moreover, with regard to the DWC Guidelines, the methodology applied is the MTUS methodology as contained in section 9792.25(c)(1), and explained in Appendix B, which is part of the rulemaking file.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Statement of conflicts of interests of the committee, commenter states that the Chronic Pain Medical Treatment Guidelines does not contain a statement of conflicts of interests of the committee as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Agree in part.** See response to comment submitted by Jeffrey S. Harris, M.D., regarding transparency and conflicts of interests dated August 11, 2008.	See action in response to comment submitted by Jeffrey S. Harris, M.D., regarding transparency and conflicts of interests dated August 11, 2008.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Disagree with regard to the direct comparison to the ACOEM Chronic Pain Update for the reasons set forth in the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, it is emphasized that the AGREE Instrument does not require publishing of the disclosures within the guidelines themselves. ODG screens contributors for potential conflicts and all affiliations. Complete CVs are available on request and are available upon request by email from the ODG Helpdesk, at ODG@worklossdata.com.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Peer-reviewers listed, commenter states that the Chronic Pain Medical Treatment Guidelines does not contain a list of its peer-reviewers as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Commenter states that the Chronic Pain Medical Treatment Guidelines does not contain a list of its peer-reviewers as opposed to the ACOEM Chronic Pain Update. This issue was addressed by the review of RAND in its 2005 Report and ODG met RAND's review that ODG complied with the AGREE Instrument domain of Rigor, specifically on external peer review. (See, 2005 RAND Report, p. xx, and ODG's Appendix B—	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			ODG Treatment in Workers' Comp, Methodology Description Using the AGREE Instrument, p. 17.) Moreover, the Chronic Pain Medical Treatment Guidelines are reviewed via the formal regulation process which requires public comments by the regulated public, and DWC takes these comments into consideration in arriving at the final regulations.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Peer-review societies listed, commenter states that the Chronic Pain Medical Treatment Guidelines does not contain a list of the peer-review societies as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Also, see response above.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Committee members listed, commenter states that the Chronic Pain Medical Treatment Guidelines does not contain a list of its committee members as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, it is noted that a list of the members of the participating MEEAC members was made available to the public on a DWC newline dated March 2, 2007 (http://www.dir.ca.gov/dwc/dwc_newslines/2007/Newsline_20-07.html), but will be made permanently available in a list constantly updated in the DWC website at DWC web site at http://www.dwc.ca.gov.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain	Under the heading Methodology and subheading Sources of the original manuscript, commenter states that Part I of the DWC Chronic Pain Medical Treatment Guidelines is an original document.	James E. Lessenger, M.D. August 4, 2008	**Agree in part. Agree** with the comment that Part I of the Chronic Pain Medical Treatment Guidelines is original and Part 2 is	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chapter	Commenter further states that Part 2 of the DWC Chronic Pain Medical Treatment Guidelines is a combination of ODG Guidelines and the Colorado Guidelines. Commenter further states that these sources "are cited but without attribution that it was copied." Commenter adds that the ACOEM Chronic Pain Update is completely original.		largely adapted from ODG, which is well documented in the ISOR. (See, ISOR pp. 42-43, and Appendix A.) The Acupuncture Medical Treatment Guidelines are adapted from the Colorado Guidelines and are not part of the Chronic Pain Medical Treatment Guidelines. **Disagree** with the remaining comment for the reasons set forth in the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Pain specialist on committee, commenter states that it is unknown whether DWC has a pain specialist on the committee which participated in the formulation of the Chronic Pain Medical Treatment Guidelines. Commenter adds that ACOEM has a pain specialist on its committee.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, it is noted that the composition of the committee is found in section 9792.26(a)(2). Pursuant to section 9792.26(a)(2)(G), the committee must contain at least one pain specialist.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Updates, commenter states that he is unsure how the DWC Chronic Pain Medical Treatment Guidelines will be updated. Commenter surmises that given the cumbersome regulatory process of the DWC, updates and corrections of dosing and other errors will undoubtedly be few and far between. Commenter adds that the ACOEM Chronic Pain Update is updated every three years with more frequent updates in the monthly Insights as needed.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Any changes to the MTUS,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			including the Chronic Pain Medical Treatment Guidelines, will be made through formal rulemaking process as required by law in the State of California.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Clearly defined recommendation categories, commenter states that the DWC Chronic Pain Medical Treatment Guidelines do not contain clearly defined recommendation categories as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, commenter states that the Chronic Pain Medical Treatment Guidelines does not contain clearly defined recommendation categories. This issue was addressed by the review of RAND in its 2005 Report and ODG met RAND's review that ODG complied with the AGREE Instrument domain of Clarity and Presentation. (See, 2005 RAND Report, p. xx, and ODG's Appendix B—ODG Treatment in Workers' Comp, Methodology Description Using the AGREE Instrument, p. 18.) The AGREE instrument in assessing Clarity and Presentation takes into consideration how treatment recommendations are structured and written. In the ODG Guidelines, where there is sufficient evidence, every topic begins with either "Recommended" or "Not recommended." The DWC	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Guidelines follows the same pattern in the clarity category.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Recommendation categories, commenter states that it is unknown whether the DWC Chronic Pain Medical Treatment Guidelines contain recommendation categories. Commenter states that the DWC Chronic Pain Medical Treatment Guidelines contain no clear standardized categories. Commenter adds the ACOEM Chronic Pain Update contains nine (9) standardized and defined categories.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, see response above.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Clearly defined data grading, commenter states that the DWC Chronic Pain Medical Treatment Guidelines do not contain clearly data grading as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, with regard the Work Loss Data Institute, the ODG grading system is incorporated as a document relied upon and is made part of the rulemaking file (See, Explanation of Medical Literature Ratings, http://www.odg-twc.com/odgtwc/ExplanationofMedicalLiteratureRatings.htm) With regard to DWC's, the MTUS grading system is found in section 9792.25(c)(1)(A). The interaction of these two grading systems is explained at length in the response to the comment regarding 9792.25(c)(1)/ Grading Methodology, submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			dated August 12, 2008, below.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Clarity recommendations, commenter states that the DWC Chronic Pain Medical Treatment Guidelines are not clear in their recommendations as opposed to the ACOEM Chronic Pain Update which is extremely clear.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. See also, response to comment regarding recommendation categories above.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading Methodology and subheading Data sources, commenter states that the DWC Chronic Pain Medical Treatment Guidelines cites consensus conferences and non-peer reviewed publications (ex. Pg 36) as the data source. Commenter also adds that the DWC Chronic Pain Medical Treatment Guidelines uses state regulation as a reference for acupuncture and not scientific literature, quotes manufacturer promotional sales literature, and uses websites as sources. Commenter adds that the ACOEM Chronic Pain Update uses peer-reviewed journal articles, guidelines, high quality review articles, and randomized controlled studies as its data source.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the references that the commenter refers to comply with ODG's system in evaluating medical literature, which are explained in their explanatory literature. (See, Explanation of Medical Literature Ratings, http://www.odg-twc.com/odgtwc/ExplanationofMedicalLiteratureRatings.htm., which is a document relied upon and added to the rulemaking file). The Acupuncture Medical Treatment Guidelines are adapted from the Colorado Guidelines and are not part of the Chronic Pain Medical Treatment Guidelines.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Length (pages), commenter states that the DWC Chronic Pain Medical Treatment Guidelines is 83 pages and the ACOEM Chronic Pain Update is 249 pages, in addition to references and appendices.	James E. Lessenger, M.D. August 4, 2008	**Agree in part.** Agree with the comment that the DWC separated the bibliography from the text of the guideline with the goal of streamlining the document for the benefit of the public.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Disagree with the comment that the length of the guideline makes it superior for the reasons set forth in the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Available, commenter states that it is unknown when the DWC Chronic Pain Medical Treatment Guidelines will be available. He opines that the regulatory process is ponderous and complicated. Commenter adds that the ACOEM Chronic Pain Update will be available in the fall of 2008.	James E. Lessenger, M.D. August 4, 2008	**Agree in part. Agree** that the DWC Chronic Pain Medical Treatment Guidelines will be available when the formal rulemaking process is complete. **Disagree** that the rulemaking process is "ponderous and complicated and just because the ACOEM Chronic Pain Update will be available in the fall of 2008," they should be adopted. Regardless of when the ACOEM Chronic Pain Update is available DWC is required is required to go through the rulemaking process. **See also,** the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading References (number), commenter states that Part 1 of the DWC Chronic Pain Medical Treatment Guidelines contains 13 references. Commenter also states that Part 2 uses, but does not list the references. Commenter opines that this point is a "fatal flaw." He further opines that the lack of a reference list is unacceptable. Commenter adds that the ACOEM Chronic Pain Update contains 1300 plus references and each appendix has its own reference section.	James E. Lessenger, M.D. August 4, 2008	**Agree in part. Agree** that the references have been removed from the text of both Part I and Part II of the Guidelines. This was done intentionally to control the length of the Chronic Pain Medical Treatment Guidelines. However, the references have been incorporated by reference as subdivision (f) of section 9792.24.2, and will be made	Subdivision (f) is added to section § 9792.24.2 as follows: "Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers' Compensation and Official Disability Guidelines References—is incorporated by reference

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			available to the public from the DWC's Medical Unit or from the DWC's website. **Disagree** with remaining comment for the reasons set forth in the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above.	into the MTUS as supplemental part of the Chronic Pain Medical Treatment Guidelines. A copy of Appendix D may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov."
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Parts of sections, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains 2 sections as opposed to the ACOEM Chronic Pain Update which has 9 sections, plus 5 algorithms, references, and 5 appendices.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Although the comment is essentially correct, it does not include a specific recommendation. DWC believes that two sections are sufficient to cover the necessary material along with the supporting documents.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Summary of table recommendations for diagnostic testing, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain a summary of table of recommendations for diagnostic testing. Commenter adds that the ACOEM Chronic Pain Update has a summary of table of recommendations for diagnostic testing, which is 3 parts: CRPS, Neuropathic pain, and Chronic persistent pain.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Although the comment is	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			essentially correct, commenter does not offer a specific recommendation.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Summary table of recommendations for management of chronic pain, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain a summary table of recommendations for management of chronic pain. Commenter adds that the ACOEM Chronic Pain Update has a summary table of recommendations for management of chronic pain, which is broken into 3 parts: recommended, no recommendation, and not recommended.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Although the comment is essentially correct, commenter does not offer a specific recommendation.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Summary of recommendations and evidence, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain a summary of recommendations and evidence while the ACOEM Chronic Pain Update does.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Although the comment is essentially correct, commenter does not offer a specific recommendation.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading "Red Flag" list and definitions, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain a "Red Flag" list and definitions while the ACOEM Chronic Pain Update does.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Although the comment is essentially correct, commenter does not offer a specific recommendation. The definitions are listed at the beginning of the regulations. (See section 9792.20) A list of red flag conditions are contained in the clinical topic sections as they are specific to the body parts.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Non-Red Flag list and definitions, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain a non-red flag list and definitions while the ACOEM Chronic Pain Update does.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Commenter is not clear as to precisely what is meant by a "Non-Red Flag." An early use of the Red Flag concept came from the original AHCPR guidelines and the meaning of this term has not changed from the original intention, i.e., a Red Flag is a clinical sign, symptom, suspicion, or indicator that there is a potentially serious condition. However, there is no established definition for flags other than red. Commenter did not make an explicit explanation for these other flags.	None.
9792.24.2 Direct Comparison to ACOEM	Under the heading General Content and subheading Number of treatment algorithms, commenter states that the DWC Chronic Pain Medical Treatment	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Barry Eisenberg, Executive Director, ACOEM, dated August 7, 2008, on	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chronic Pain Chapter	Guidelines does not contain treatment algorithms while the ACOEM Chronic Pain Update contains 5.		the issue of 9792.24.2 General/Lack of Algorithms, above.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Appendices, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain appendices while the ACOEM Chronic Pain Update contains five (5) opioids, fibromyalgia, pain history questions, psychological testing, and a review of low quality studies and guidelines.	James E. Lessenger, M.D. August 4, 2008	**Agree in Part. Agree** that Appendix D (Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers' Compensation and Official Disability Guidelines' References) containing the References in support of the Chronic Pain Medical Treatment Guidelines should be part of the regulations and they have been incorporated by reference as reflected in proposed subdivision (f) of section 9792.25.2 as previously discussed. **Disagree** that Appendix B (Appendix B—Chronic Pain Medical Treatment Guidelines-Evidence-Based Reviews) should be incorporated into the regulations because it is not necessary at this point. After the Notice of Proposed Rulemaking issued in June of 2007 and during the 45-day comment period, the editors of the Work Loss Data Institute revised the ODG Guidelines and performed their own evidence-based reviews (EBRs). Those EBRs included DWC's EBRs. Accordingly, it is not necessary to have DWC's EBRs in Appendix B incorporated into the regulations as they have been absorbed by ODG's EBRs, and are included in their guidelines	Subdivision (f) is added to section § 9792.24.2 as follows: "(f) Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers' Compensation and Official Disability Guidelines References—is incorporated by reference into the MTUS as supplemental part of the Chronic Pain Medical Treatment Guidelines. A copy of Appendix D may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov."

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			and are part of the Chronic Pain Medical Treatment Guidelines, Part 2. Moreover, **Disagree** with the remaining comment for the reasons set forth in the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Discussion of the initial assessment, commenter states that the discussion of the initial assessment in the DWC Chronic Pain Medical Treatment Guidelines is superficial while in the ACOEM Chronic Pain Update it is comprehensive.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, DWC is satisfied that Part I of its Chronic Pain Medical Treatment Guidelines is a proper introduction to the chronic pain guidelines and it is not meant to be a textbook.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Discussion of causation analysis, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains no discussion of causation analysis while the ACOEM Chronic Pain Update does.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. It is noted, moreover, that causation is a complex medical-legal issue that is beyond the scope of the Chronic Pain Medical Treatment Guidelines. These guidelines help	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			determine medical necessity and treatment, not causation.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Discussion of the initial history and physical examination, commenter states that the discussion of the initial history and physical examination in the DWC Chronic Pain Medical Treatment Guidelines is superficial (half a page) while the discussion in the ACOEM Chronic Pain Update is detailed and extensive (8 pages).	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Moreover, DWC is satisfied that Part I of its Chronic Pain Medical Treatment Guidelines is a proper introduction to the chronic pain guidelines and it is not meant to be a textbook.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Index, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain an index while the ACOEM Chronic Pain Update does.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Although the comment is essentially correct, the chronic pain medical treatment guidelines are organized alphabetically and some topics are grouped under a heading. Given this organization an index is unnecessary.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain	Under the heading General Content and subheading Definitions (number), commenter states that Part 1 of the DWC Chronic Pain Medical Treatment Guidelines contains 4 definitions and Part 2 contains 1 definition.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chapter	Commenter adds that the ACOEM Chronic Pain Update contains 31 definitions in a separate section.		dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. It is noted that the concept of definitions has a special significance in the regulatory context. The regulations contain specific definitions in section 9792.20, and Part 1 of the Chronic Pain Medical Treatment Guidelines also contains definitions.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Number of diagnostic studies reviewed, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains 3 diagnostic studies reviews while the ACOEM Chronic Pain Update contains 14.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. Moreover, see response to comment submitted by Jeff Harris, M.D., on section 9792.24.2, General/Diagnostic tests, dated August 11, 2008, above.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Number of interventions reviewed, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains 53 interventions reviews while the ACOEM Chronic Pain Update contains 69 categories with up to 7 evaluations in each category.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
9792.24.2	Under the heading General Content and subheading	James E. Lessenger,	**Disagree.** See response to Francis	None

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Direct Comparison to ACOEM Chronic Pain Chapter	Number of medication classes reviewed, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains 23 medication classes reviews while the ACOEM Chronic Pain Update contains 24.	M.D. August 4, 2008	Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Recommendations clearly set apart, commenter states that the recommendations in the DWC Chronic Pain Medical Treatment Guidelines are not clearly set apart. He indicates that they are embedded into the discussion and difficult to pick out. Commenter adds that the recommendations in the ACOEM Chronic Pain Update are clearly set apart and highlighted.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Basic principles discussed, commenter states that in both guidelines the basic principles are discussed.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Discussions of the literature upon which the recommendations were made, commenter states that the discussions of the literature upon which the recommendations were made in the DWC Chronic Pain Medical Treatment Guidelines are minimal. He indicates that they are substantial and thorough in the ACOEM Chronic Pain Update.	James E. Lessenger, M.D. August 4, 2008	**Agree in Part. Agree** that the literature upon which the recommendations were made in the Chronic Pain Medical Treatment Guidelines should be made part of the regulations. Appendix D, containing the References in support of the Chronic Pain Medical Treatment Guidelines, should be part of the regulations and they have been incorporated by reference as reflected in	Subdivision (f) is added to section § 9792.24.2 as follows: "(f) Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers' Compensation and Official Disability Guidelines References—is incorporated by reference into the MTUS as

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			proposed subdivision (f) of section 9792.25.2. **Disagree** that Appendix B (Appendix B—Chronic Pain Medical Treatment Guidelines-Evidence-Based Reviews) should be incorporated into the regulations because it is not necessary at this point. After the Notice of Proposed Rulemaking issued in June of 2007 and during the 45-day comment period, the editors of the Work Loss Data Institute revised the ODG Guidelines and performed their own evidence-based reviews (EBRs). Those EBRs included DWC's EBRs. Accordingly, it is not necessary to have DWC's EBRs in Appendix B incorporated into the regulations as they have been absorbed by ODG's EBRs, and are included in their guidelines and are part of the Chronic Pain Medical Treatment Guidelines, Part 2. Moreover, **Disagree** with the remaining comment for the reasons set forth in the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	supplemental part of the Chronic Pain Medical Treatment Guidelines. A copy of Appendix D may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov."
9792.24.2	Under the heading General Content and subheading	James E. Lessenger,	**Disagree.** See response to Francis	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Direct Comparison to ACOEM Chronic Pain Chapter	Review of pain pathophysiology, commenter states that both guidelines contain a review of pain pathophysiology.	M.D. August 4, 2008	Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Discussion of risk factors for chronic pain, commenter states that both guidelines contain a discussion of risk factors for chronic pain.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Review of treatment models, Commenter states that the DWC Chronic Pain Medical Treatment Guidelines review 5 treatment models. He indicates that the ACOEM Chronic Pain Update reviews one treatment model: biopsychosocial model.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Summary of recommendations and evidence, commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not contain a summary of recommendations and evidence while the ACOEM Chronic Pain Update does.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
9792.24.2 Direct Comparison to ACOEM	Under the heading General Content and subheading Portability, commenter states that the DWC Chronic Pain Medical Treatment Guidelines can be folded and	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chronic Pain Chapter	put into a coat pocket like a racing program. Commenter adds that the ACOEM Chronic Pain Update is in book form, but the web form will be available for "cut and paste." Commenter adds that a collection of the summary tables would make a useful booklet.		Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading General Content and subheading Dosing information, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains dosing information. He opines that it is inappropriate for the DWC to impinge on the power and authority of the Federal Government and the FDA to set dosage guidelines. He believes that there is a great tendency for error in this area and the method of correction of errors in this system is cumbersome. He believes this is dangerous. He indicates that there is no efficient and rapid method of making changes to update new information or to correct errors. Commenter adds that the ACOEM Chronic Pain Update has dosing information for opioids. He adds that for other treatments, the frequency, duration, interactions, side effects, rational for recommendation and indications for discontinuation are given for each recommended medication.	James E. Lessenger, M.D. August 4, 2008	**Agree in Part. Agree** that the Chronic Pain Medical Treatment Guidelines should contain language regarding dosing information. In that regard, The fifth Paragraph, under Functional Restoration Approach to Chronic Pain Management, is modified to insert a fifth sentence, stating, "The physician should be knowledgeable regarding prescribing information and adjust the dosing to the individual patient." **Disagree** with the remaining comment for the reasons set forth in the response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	The fifth paragraph, under the subject Functional Restoration Approach to Chronic Pain Management, at page 8, is modified by inserting a new sixth sentence in the middle of the paragraph. The new sentence states: "If the physician prescribes a medication for an indication not in the approved FDA labeling, he or she has the responsibility to be well informed about the medication and that its use is scientific and evidence-based."
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the General Content heading, commenter offers the following comments:	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Off label dosing information Commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains off-label dosing information. Commenter opines that it is inappropriate for the DWC to impinge on the power and authority of the Federal Government and the FDA to authorize "off label" prescribing guidelines in State regulation. Commenter states that DWC offers citations but no reference lists as to their rationale for this. He believes this is dangerous. Commenter adds that the ACOEM Chronic Pain Update offers no off-label dosing information.		substantively address the proposed changes to the medical treatment utilization schedule regulations. Moreover, commenter is incorrect in stating that off label dosing is not allowed by the FDA. In that regard, the FDA states: "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight. (http://www.fda.gov/OC/OHRT/IRBS/offlabel.html)	
9792.24.2 Direct Comparison	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the	James E. Lessenger, M.D.	**Agree in Part. Agree** that clarifying language should be	The fifth paragraph, under the subject Functional

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
to ACOEM Chronic Pain Chapter	Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the General Content heading, commenter offers the following comments: Off-label drug use indicated as such Commenter states that the DWC Chronic Pain Medical Treatment Guidelines discusses off-label drug use indicated as such but in an inconsistent manner. He further adds that the DWC Chronic Pain Medical Treatment Guidelines contains no disclaimer regarding off-label drug use. Commenter adds that the ACOEM Chronic Pain Update discusses off-label drug use indicated as such and indicates that all chapters include analyses of numerous interventions, whether or not FDA-approved. For non-FDA-approved interventions, recommendations are based on the available evidence; however, this is not an endorsement of their use. In addition, many of the medications recommended are utilized off label.	August 4, 2008	inserted in the Introduction to advise physicians that (1) they should know the prescribing information for drugs, (2) that if they are prescribing a medication for an indication not in the approved FDA labeling, they have the responsibility to be well informed about the medication and that use. The fifth paragraph, under the subject Functional Restoration Approach to Chronic Pain Management, at page 8, is modified by inserting a new sixth sentence in the middle of the paragraph, stating: "If the physician prescribes a medication for an indication not in the approved FDA labeling, he or she has the responsibility to be well informed about the medication and that its use is scientific and evidence-based." **Disagree** with the comment that by including off label drug use in the MTUS that represents an endorsement of such use. Rather, the MTUS provides information concerning the scientific and evidence-based recommendation for off-label use.	Restoration Approach to Chronic Pain Management, at page 8, is modified by inserting a new sixth sentence in the middle of the paragraph. The new sentence states: "If the physician prescribes a medication for an indication not in the approved FDA labeling, he or she has the responsibility to be well informed about the medication and that its use is scientific and evidence-based."
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the General Content heading, commenter offers the following comments:	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Costs Commenter states that the DWC Chronic Pain Medical Treatment Guidelines is presumably free online through the DWC website. Commenter adds that a printed copy of the ACOEM Chronic Pain Update is $59.95, and online access to all the ACOEM Guidelines is $199 a year.		substantively address the proposed changes to the medical treatment utilization schedule regulations. Although the comment is essentially correct, commenter offers no recommendation. The DWC Chronic Pain Medical Treatment Guidelines will be available at no cost online through the DWC website. The cost of the ACOEM guideline is outside of the scope of this guideline.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the Summary heading, commenter offers the following comments: Commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not reflect well upon the medical profession. Commenter adds that the ACOEM Chronic Pain Update is comprehensive and authoritative. Commenter adds that it is new, freshly evaluated data.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the Summary heading, commenter offers the following comments: Advantages Commenter states that the DWC Chronic Pain Medical Treatment Guidelines is short, portable, and free. Commenter adds that the ACOEM Chronic Pain Update is comprehensive and authoritative. It can be downloaded to a palm pilot. It contains algorithms,	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	list charts. Commenter adds that it uses only high or moderate quality randomized control trials (RCTs), systemic review articles, review articles, and other high quality articles. Commenter also states when the guidelines uses low grade RCTs, they are labeled as such.			
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the Summary heading, commenter offers the following comments: Disadvantages Commenter states that the DWC Chronic Pain Medical Treatment Guidelines is superficial, it contains no charts or lists for quick reference, it is not comprehensive, lacks authoritative vigor, and lacks scientific creditability. Commenter states that the guidelines use consensus conference data and non-peer reviewed articles. Commenter adds that the ACOEM Chronic Pain Update is too bulky to easily carry around, and costs money to the user.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** See response to Francis Riegler, M.D., President, California Society of Interventional Pain Physicians, dated August 11, 2008, above. Moreover, the comment does not substantively address the proposed changes to the medical treatment utilization schedule regulations. With regard to commenter's opinion that the DWC Chronic Pain Medical Treatment Guidelines are superficial, commenter does not offer a specific example of the guidelines he considers superficial. Thus, his comment is non-responsive. With regard to his comment that the DWC Chronic Pain Medical Treatment Guidelines contains no charts or quick references, DWC is not clear whether commenter is referencing the ACOEM algorithms. If commenter is addressing this issue, see response to Barry Eisenberg, Executive Director, ACOEM, dated August 7, 2008 on the issue of section 9792.24.2/General/Lack of	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Algorithms, above. Moreover, commenter argues that the DWC Chronic Pain Medical Treatment Guidelines lack authoritative vigor and lack scientific creditability. With regard to this comment, see response to comment submitted by Steven C. Schumann, M.D., Legislative Chair, Western Occupational & Environmental Medicine Association, A Component Society of ACOEM, August 12, 2008, on the issue of section 9792.20(e)/Evidence-based concept, above. Commenter also argues that the guidelines use consensus conference data and non-peer reviewed articles. In this regard, please refer to the response to James E. Lessenger, M.D., dated August 4, 2008 on the issue of 9792.24.2, Comparison to ACOEM Chapter/Consensus Issue, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction**	Commenter suggests that the term "red flag" in the introduction be substituted with the term "emergent alert" in the first sentence of the first paragraph of the introduction.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The term "red flag" is a term used through the MTUS to refer to a serious medical condition or diagnosis. The term was originally used by the former Agency for Health Care Policy and Research Clinical Practice Guideline No. 14 on Acute Low Back Problems in Adults. Although the guideline is no longer	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			current, the language contained in that guideline is instructive. It states: "The initial assessment of patients with acute low back problems focuses on the detection of "red flags" (indicators of potentially serious spinal pathology or other nonspinal pathology)" (http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.25870) Moreover, ACOEM extends the use of "red flags" in the ACOEM Practice Guidelines, 2nd Edition, in its 2nd chapter entitled General Approach to Initial Assessment and Documentation, at p. 21, wherein it defines the term "red flag" as a "nonperjorative term that refers only to serious medical conditions." Following the introduction of the term "red flags" the ACOEM Practice Guidelines, use the "red flags" in each chapter that provides medical treatment guidelines for specific body parts. For example in Chapter 8 "neck and upper back complaints" "red flag" is used in the master algorithm, in the introductory text on the first page of the chapter, and in a specific section titled "Assessing Red Flags and Indications for Immediate Referral," and in the initial	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			algorithm. Also, the Official Disability Data Guidelines (ODG) uses the term "red flags" to identify serious medical conditions in their body part chapters such as low back, knee, and shoulder. It is noted, however, that ODG's Pain chapter uses the "red flags" term to also describe situations involving addiction.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction**	Commenter suggests that the third sentence of the first paragraph of the introduction be amended to reflect reassessment of the patient over "the next 2-4 weeks" instead of over "the next 3-4 weeks" as reflected in the text of the introduction.	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** that providing for a time frame for reassessment may not be appropriate. The interval or clinical circumstances for reassessment should be left to the judgment of the physician. Thus the third and fourth sentences of the first paragraph of the Introduction will be amended to state "Upon ruling out a potentially serious condition, conservative management is provided. If the complaint persists, the physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary."	The third and fourth sentences of the first paragraph of the Introduction, at page 1, will be amended to state as follows: "Upon ruling out a potentially serious condition, conservative management is provided ~~and the patient is reassessed over the next 3-4 weeks~~. If the complaint persists ~~during this interval~~, the physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction**	Commenter suggests that the phrase "treatment augmentation" be inserted after the word "reconsider" in the fourth sentence of the first paragraph of the introduction. Thus, the sentence would read as follows: "If the complaint persists during this interval, the physician needs to reconsider <u>treatment augmentation</u>, the diagnosis and decide whether a specialist evaluation is necessary."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** When a patient is not improving with the initial course of treatment, the physician must reconsider the diagnosis as the initial diagnostic impression may be incorrect. Once the diagnosis is reformulated, then additional treatment may be considered.	None.
9792.24.2(a) Chronic Pain	Commenter suggests that the word "or" be inserted instead of the word "and" in the fourth sentence of the	Robert L. Barkin, PharmD, M.B.A.	**Disagree**. Both reconsideration of the diagnosis AND deciding	None.

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Medical Treatment Guidelines **Part I: Introduction**	first paragraph of the introduction. Thus, the sentence would read as follows: "If the complaint persists during this interval, the physician needs to reconsider the diagnosis "or" decide whether a specialist evaluation is necessary."		whether a specialist evaluation is necessary are both required. It is at the discretion of the physician to decide whether a referral is necessary whenever he or she is reconsidering a diagnosis and whether to seek additional opinions.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Definitions**	Commenter suggests that the definition of "chronic pain" be amended as "*any pain that persists beyond the anticipated time of tissue healing* or a chronic musculoskeletal neuropathic painful diagnosis."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** With regard to the definition of the term "chronic pain" as set forth in proposed section 9792.20(c), see response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, above. **Disagree** with the commenter that the phrase "or a chronic musculoskeletal neuropathic painful diagnosis" should be added to the definition of "chronic pain." The definition of chronic pain encompasses those diagnoses that may be considered chronic conditions at the time of initial diagnoses, that includes musculoskeletal neuropathic conditions, but also painful neuropathy, migraine headaches, and other such painful conditions where the painful condition is expected to persist.	See action taken in connection with response to comment submitted by Brenda Ramirez regarding Section 9792.20(c).
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter references the Types of Pain subtitle under the Definitions title at page 1 of the Introduction. Commenter references the sentence which states: "Pain mechanisms can be broadly	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** In its Chronic Pain Medical Treatment Guideline, the DWC chose to define pain by a neuroanatomic conceptual	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part I: Introduction Definitions	categorized as nociceptive or neuropathic." Commenter edits this sentence to add in the categorization of pain mechanisms "ischemic, somatic, and visceral."		framework, i.e., nociceptive vs. neuropathic pain. Nociceptive mechanisms are inclusive of regional anatomic characterizations of pain such as visceral vs. somatic, as well as by pain mechanisms such as ischemic, inflammatory, and mechanical. (See, Mackey, S. C. and F. Maeda (2004). "Functional imaging and the neural systems of chronic pain." Neurosurg Clin N Am 15(3): 269-88.)	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Overview**	Commenter references the Overview subtitle under the Introduction at page 1 of the Introduction. Commenter edits the second sentence of the first paragraph under that subtitle as follows: "~~Most~~ C~~c~~hronic pain problems start with an acute nociceptive pain episode or function of a chronic debilitating painful disease process."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Not necessary to modify the sentence as suggested by commenter. The intent of the overview is to recognize that most chronic pain begins as an acute episode and, therefore, it is important to recognize chronicity amongst cases that present acutely so that management of chronic pain can begin early in the course of treatment.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Overview**	Commenter references the Overview subtitle under the Introduction at page 1. Commenter edits the third sentence of the first paragraph under that subtitle as follows: "Therefore, effective early care is paramount in ~~preventing~~ abating chronic pain. Commenter indicates that the word "abating" is better because the condition may progress.	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** Early recognition of chronicity is important to provide effective care. DWC agrees that the use of the concept "prevention" is not correct because we cannot be certain in any given case that a worse outcome would have occurred absent the intervention. However, the concept "abatement" raises similar issues. We believe, however, that the concept of "management" is better because early recognition of chronicity does change the	The third sentence of the first paragraph of the Overview of the Introduction of the Chronic Pain Medical Treatment Guidelines has been amended to read as follows: "Therefore, effective early care is paramount in managing chronic pain."

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			management approach in treating the chronic condition.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Overview**	Commenter references the Overview subtitle under the Introduction at page 1 of the Introduction. . Commenter edits the second sentence of the 2nd paragraph under that subtitle as follows: "This describes pain as a subjective experience; therefore, unlike hypertension or diabetes, there is no objective measurement for chronic pain intensity."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** modifying the word pain in this sentence because the reference in this sentence is to the intensity of the pain not the type of the pain. The insertion of the word "chronic" to modify the concept of "pain intensity" alters the meaning of the statement which reflects all pain types, acute or chronic.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Overview**	Commenter references the Overview subtitle under the Introduction at page 1 of the Introduction. Commenter edits the third sentence of the 2nd paragraph under that subtitle as follows: "Analysis of the objective data (psychosocial assessment, physical exam findings, imaging results, lab tests) is needed to evaluate the extent of the patient's subjective report of pain."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter is incorrect in stating that an objective test can be used to evaluate the extent of subjective pain. "Unfortunately, unlike many diseases we treat, such as hypertension or diabetes, there is no direct reproducible measurement we can make to measure a patient's pain." Mackey, S. C. and F. Maeda (2004). "Functional imaging and the neural systems of chronic pain." Neurosurg Clin N Am 15(3): 269-88, at p.1.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Overview** Pain Mechanisms	Commenter references the Pain Mechanisms subtitle under the Introduction at page 3 of the Introduction. Commenter edits the second sentence of the 1st paragraph under that subtitle as follows: "While there may be ~~are~~ some overlap and similarities, each mechanism has unique features and characteristics.	Robert L. Barkin, PharmD, M.B.A.	**Disagree**. Edits do not enhance the text of the guidelines.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter references the Pain Mechanisms subtitle under the Introduction at page 3 of the Introduction. Commenter edits the paragraph No. 5 under that subtitle as follows: "Neuropathic pain is characterized	Robert L. Barkin, PharmD, M.B.A.	**Agree in part**. There are many more terms that can describe what might be considered neuropathic pain. DWC has modified	Paragraph No. 5 under the subtitle Pain Mechanisms of the Introduction of the Chronic Pain Medical

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part I: Introduction Overview Pain Mechanisms	by such symptoms as lancinating, electric shock, paroxysmal, tingling, numbness, and burning sensations that are distinct from nociceptive pain.		paragraph No. 5 under the subtitle Pain Mechanisms to include the additional words of "electric shock-like" and "numbing" which are contained in the lexicon of neuropathic pain symptoms. Thus, paragraph No. 5 now states: "Neuropathic pain is characterized by symptoms such as lancinating, electric shock-like, paroxysmal, tingling, numbing, and burning sensations that are distinct from nociceptive pain."	Treatment Guidelines at page 3 has been amended to state: "Neuropathic pain is characterized by symptoms such as lancinating, electric shock-like, paroxysmal, tingling, numbing, and burning sensations that are distinct from nociceptive pain."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Overview** Pain Mechanisms	Commenter references the Pain Mechanisms subtitle under the Introduction at page 3, paragraph 6. Commenter edits the third sentence as follows: "These conditions include but are not limited to chronic low back pain (CLBP), fibromyalgia, irritable bowel syndrome, diabetic neuropathy, and Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD). (Mackey and Maeda 2004)."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** We **agree** with commenter that there are additional conditions which are not included in the list provided for in the referenced article of Mackey and Maeda 2004. In light of this, we have changed the specific sentence referred to by the commenter as follows: "These conditions include, but are not limited to, chronic low back pain (CLBP), fibromyalgia, irritable bowel syndrome, and Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD)." The changed sentence acknowledges that there may be other chronic pain conditions that have a large centralized component, such as diabetic neuropathy. **Disagree** that DWC can add another example to the text of the Introduction. Because the text of the Introduction is referencing a	The third sentence at paragraph 6, page 3, under subtitle Pain Mechanisms following the Introduction of the Chronic Pain Medical Treatment Guidelines is amended as follows: "These conditions include, but are not limited to, chronic low back pain (CLBP), fibromyalgia, irritable bowel syndrome, and Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD)."

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			source, DWC can only report what the source states, and it cannot add additional examples. The Mackey and Maeda 2004 study was carried out for the above referenced conditions. Mackey, S. C. and F. Maeda (2004). "Functional imaging and the neural systems of chronic pain." Neurosurg Clin N Am 15(3): 269-88, at page 2.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models**	Commenter references the section subtitled "Models" under the Introduction at page 4. Commenter edits the first two sentences of the first paragraph of this section as follows: "Models are the conceptual framework for physicians, patients, families, healthcare ~~facilities~~ providers, carriers, and compensation systems in an attempt towards the ~~for~~ understanding of pain. Models ~~help~~ provide a framework to establish parameters for reasonable outcomes and acceptable standards of care."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** with commenter that "facilities" is an incorrect term and that we are referring to the different participants in the workers' compensation system who need a conceptual framework. A conceptual framework does not include a facility. Similarly, a model does not "help" but rather is a representation of a concept hence "models" provide a framework. **Disagree** with the remaining suggested re-drafting of the sentence as the entire paragraph has been redrafted by DWC for clarification purposes. The first paragraph of the section subtitled "Models" under the Introduction is re-drafted for clarification purposes to clarify what models represent and who will use them. Accordingly, The first paragraph of the section subtitled "Models" under the Introduction at page 4 is amended as follows: "Models are the conceptual framework to	The first paragraph of the section subtitled "Models" under the Introduction at page 3 is amended as follows: "Models are the conceptual framework to understand pain and serve to establish parameters for reasonable outcomes and acceptable standards of care. These are helpful for physicians, patients, families, healthcare providers ~~facilities~~, carriers, and compensation systems ~~for understanding pain~~. ~~Models help to establish parameters for reasonable outcomes and acceptable standards of care~~. Several different models of pain have developed over time, each with ~~insights and limitations~~ strengths and weaknesses."

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			understand pain and serve to establish parameters for reasonable outcomes and acceptable standards of care. These are helpful for physicians, patients, families, healthcare providers, carriers, and compensation systems. Several different models of pain have developed over time, each with strengths and weaknesses."	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction. Commenter edits the first sentence of the first paragraph as follows: "In many situations, acute pain serves as a highly adaptive and beneficial protective experience."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** We **agree** with the commenter that the word "protective" is a useful concept due to its protective nature. We believe, however, that the placement of the word "protective" is better for contextual purposes to be placed before the word "warning" throughout the text of the Acute vs. Chronic Pain Model section of the Introduction. Accordingly, Paragraph No. 1, sentence No. 2, and Paragraph No. 3, sentence No. 2, have been amended to read as follows: "Fundamentally, it serves as a ***protective*** warning of actual or impending tissue damage." "Whereas acute pain serves as a ***protective*** warning signal, chronic pain has no known survival benefit."	Paragraph No. 1, Sentence No. 2, at page 3, and paragraph No. 3, sentence No. 2, at page 4, of the Acute vs. Chronic Pain Model section of the Introduction, are modified as follows: "Fundamentally, it serves as a protective warning of actual or impending tissue damage. Acute musculoskeletal pain is a common example in the injured worker and is often a signal of real or impending tissue damage. "Whereas acute pain serves as a protective warning signal, chronic pain has no known survival benefit."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction. Commenter edits the second sentence of the first paragraph as follows: "Fundamentally, it serves as a	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter adds language that detracts from the main point which is that acute pain serves as a protective warning.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part I: Introduction Models Acute vs. Chronic Pain Model	warning of actual or impending tissue damage, based upon peripheral sensitization."		How that occurs might be through various mechanisms, such as peripheral sensitization.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction. Commenter edits the third sentence of the first paragraph as follows: "Acute musculoskeletal pain is a common example in the injured worker and is often a protective signal of real or impending tissue damage."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** See response to the comment submitted by the same commenter with respect to the issue of "protective" language above.	See action taken in connection with the comment submitted by the same commenter with respect to the issue of "protective" language above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction. Commenter edits the first sentence of the second paragraph as follows: "Most acute pain is self-limited ~~or~~ and responds to short term administration of analgesics and conservative therapies."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** The commenter changed the "or" to an "and". We **agree** that most acute pain is self-limited. It is also true that most acute pain responds to short term administration of analgesics and conservative therapies. Since both are true, one does not exclude the other, and therefore "or" is incorrect. By stating "and", there may be instances where acute pain is self-limited, but may not respond to short term administration of analgesics and conservative therapies, and therefore inserting "may" is more accurate. Therefore the first sentence of the second paragraph, under the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction will be amended to read as follows: "Most acute pain is self-limited and may respond to short term	The first sentence of the second paragraph of the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction of the Chronic Pain Medical Treatment Guidelines is amended as follows: "Most acute pain is self-limited ~~or~~ and may respond~~s~~ to short term administration of analgesics and conservative therapies."

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			administration of analgesics and conservative therapies."	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 3 of the Introduction. Commenter edits the second sentence of the second paragraph as follows: "However, continued activation of nociceptors with ~~poor~~ less than adequate pain control can lead ~~to~~ from peripheral ~~and~~ to possible central sensitization, a risk factor for persistent pain leading to a neuropathic pain state with prolonged disability, delayed return to baseline function, and delayed return to work."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** that the language "less than adequate," better expresses the concept as it is understood that there are tradeoffs that need to be considered in the control of pain. The tradeoffs represent a balance of the benefits or potential benefits of the intervention vs. the side effects, risks or complications. Using "less than adequate" better reflects the challenges of controlling acute pain. Poor pain control represents more extreme clinical situation. It is important to target adequate pain control as the desired goal. **Disagree** with Commenter's comment stating that "pain control can lead from peripheral to possible central sensitization." This implies a causal relation that the peripheral process causes the central process, which is incorrect. Central sensitization can occur independently or indirectly, for example when psychosocial risk factors are present modifying the pain experience. Mackey, S. C. and F. Maeda (2004). "Functional imaging and the neural systems of chronic pain." Neurosurg Clin N Am 15(3): 269-88.	The second sentence of the second paragraph of the section subtitled: Acute vs. the Chronic Pain Model, at page 3 of the Introduction of the Chronic Pain Medical Treatment Guidelines is amended as follows: "However, continued activation of nociceptors with less than adequate ~~poor~~ pain control can lead to peripheral and central sensitization, a risk factor for persistent pain leading to a neuropathic pain state with prolonged disability, delayed return to baseline function, and delayed return to work."
9792.24.2(a) Chronic Pain	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction.	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** See response to commenter's comment with	See action above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter edits the second sentence of the third paragraph as follows: "Whereas acute pain serves as a warning signal, chronic pain has no known survival beneficial protective benefit."		respect to "protective" language above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction. Commenter edits the third sentence of the third paragraph as follows: "Chronic pain is persistent and relentless, serving no ~~obvious~~ protective purpose for the individual."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** Although commenter attempts to edit the sentence, DWC has determined that sentence is redundant. Thus the sentence has been deleted from the paragraph.	The third sentence of the third paragraph in the section Acute vs. the Chronic Pain Model of the Introduction, at page 4, has been deleted.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction. Commenter edits the last sentence of the third paragraph as follows: "To complicate matters, ~~unremitting~~ chronic pain may be associated with depression and/or anxiety."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** with commenter's edit that the word "and/" should be inserted prior to the word "or" to clarify the sentence that chronic pain may be associated with depression and/or anxiety independently or concurrently because these complications may occur together. **We disagree** with commenter, however, that the word "chronic" should be inserted instead of the word "unremitting" because unremitting, and persistent pain are terms often used interchangeably with chronic pain. We chose to use alternate terminology to acknowledge that chronic pain means pain that does not go away. Accordingly, the last sentence of the third paragraph, the section subtitled: Acute vs. the Chronic	The last sentence of the third paragraph the section subtitled: Acute vs. the Chronic Pain Model, at page 4 of the Introduction of the Chronic Pain Medical Treatment Guidelines is Amended as follows: "To complicate matters, unremitting pain may be associated with depression and/or anxiety."

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Pain Model, at page 4 of the Introduction of the Chronic Pain Medical Treatment Guidelines is Amended as follows: "To complicate matters, unremitting pain may be associated with depression and/or anxiety."	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Acute vs. Chronic Pain Model	Commenter references the section subtitled: Acute vs. the Chronic Pain Model, and submits a proposed sentence at the end of the section. The proposed sentence is not legible.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC is not able to discern the meaning of commenter's edit.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Illness Behavior Model	Commenter references the section subtitled: Illness Behavior Model, at page 4 of the Introduction. Commenter adds "psychosocial issues" as an element which affects the experience of pain to the first sentence of the first paragraph of that section.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter adds "psychosocial issues" as an element which affects the experience of pain in the first paragraph which discusses the Illness Behavior Model. This addition is unnecessary as the following sentence right in the same paragraph discusses the very same issue. The sentence states: "Psychosocial factors can affect the perception and expression of pain."	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Illness Behavior Model	Commenter references the section subtitled: Illness Behavior Model, at page 4 of the Introduction. Commenter edits the third sentence of the first paragraph of that section as follows: These might include a tendency toward anxiety, depression, somatization, fear avoidance, emotional lability, catastrophizing, job dissatisfaction, patient medicated, substance abuse, and embellishment.	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** that this sentence merits clarification so that the list of illness behaviors in the sentence are not meant to be all inclusive but are meant to be illustrative. Thus the sentence is amended to state: "These might include, but are not limited to, a tendency toward anxiety,	The first sentence of the first paragraph of the section subtitled: Illness Behavior Model, at page 4 of the Introduction of the Chronic Pain Medical Treatment Guidelines is amended as follows: "These might include, but are not limited

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			depression, somatization, fear avoidance, emotional lability, catastrophizing, job dissatisfaction, and embellishment." We disagree, however, with commenter's edits adding "patient medicated, substance abuse," to the list because these items do not constitute illness behaviors. Thus, the first sentence of the first paragraph of the section subtitled: Illness Behavior Model, at page 4 of the Introduction of the Chronic Pain Medical Treatment Guidelines is amended as follows: "These might include, but are not limited to, a tendency toward anxiety, depression, somatization, fear avoidance, emotional lability, catastrophizing, job dissatisfaction and embellishment."	to, a tendency toward anxiety, depression, somatization, fear avoidance, emotional lability, catastrophizing, job dissatisfaction and embellishment."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Illness Behavior Model	Commenter references the section subtitled: Illness Behavior Model, at page 4 of the Introduction. Commenter edits the first sentence of the second paragraph of that section as follows: "Further, while frank malingering is rare, secondary gain factors, such as disability income, non compliance, and avoidance of perceived unpleasant tasks can impact the overall clinical presentation.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** It is not clear what commenter means when he states that non-compliance is a secondary gain. Non-compliance does not result in a "gain" as opposed to, for example, disability income which is a gain or avoiding the performance of perceived unpleasant task which is also a gain.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction**	Commenter references the section subtitled: Illness Behavior Model, at page 4 of the Introduction. Commenter edits the first sentence of the second paragraph of that section as follows: Efforts directed solely ~~to~~ toward the management of possible pain generators without addressing psychosocial factors	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The words "toward" and "to" mean the same in the context of the sentence.	None.

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Models Illness Behavior Model	may result in a suboptimal outcome.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Medical vs. Self-Management	Commenter references the section subtitled: Medical vs. Self-Management Model, at page 5 of the Introduction. Commenter edits the first sentence of the first paragraph of that section as follows: "Understandably, patients want their chronic pain "cured" or eliminated."	Robert L. Barkin, PharmD, M.B.A.	**Agree.** Placement in quotations adds emphasis to word "cured" as a clinical issue that arises and often voiced by the patient, or other parties. The quotation marks help to distinguish this usage of "cured" and reflects that this usage of cured is a common expression from patients with pain.	The first paragraph, first sentence, under Medical vs. Self-Management Model, of the Introduction at page 5, is modified to place the word "cured" in quotation marks. The sentence as modified states: "Understandably, patients want their chronic pain "cured" or eliminated."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Medical vs. Self-Management	Commenter references the section subtitled: Medical vs. Self-Management Model, at page 5 of the Introduction. Commenter edits the second sentence of the first paragraph of that section as follows: "Unfortunately, there are presently no definitive "cures" for the majority of persistent pain problems, such as axial spine pain, peripheral neuropathies, fibromyalgia, etc."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The use of the quotation marks in this sentence is inappropriate. While the use of the quotation marks in the earlier sentences for the word "cured" was appropriate, the meaning of the word as used in this sentence carries the regular meaning of the word (i.e., to recover) as opposed to the expression used by patients with chronic pain.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Medical vs. Self-Management	Commenter references the section subtitled: Medical vs. Self-Management Model, at page 5 of the Introduction. Commenter edits the third sentence of the first paragraph of that section as follows: "As is the case with all chronic medical conditions, chronic pain must be managed, not "cured."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The use of the quotation marks in this sentence is inappropriate. While the use of the quotation marks in the earlier sentences for the word "cured" was appropriate, the meaning of the word as used in this sentence carries the regular meaning of the word (i.e., to recover) as opposed to the expression used by patients with chronic pain.	None.
9792.24.2(a) Chronic Pain	Commenter references the section subtitled: Medical vs. Self-Management Model, at page 5 of the	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** It is unnecessary to add the word "some" before the phrase	None.

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Medical Treatment Guidelines **Part I: Introduction Models** Medical vs. Self-Management	Introduction. Commenter edits the fifth sentence of the first paragraph of that section as follows: "Currently, self-management strategies can significantly improve a patient's function and quality of life, while reducing some subjective experiences of pain."		"subjective experiences of pain." The use of the word "some" is superfluous language.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Medical vs. Self-Management	Commenter references the section subtitled: Medical vs. Self-Management Model, at page 5 of the Introduction. Commenter edits the seventh sentence of the first paragraph of that section as follows: "It is important to educate patients on this distinction, to avoid persistent and unrealistic exalted expectations for an elusive cure, where none exists."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Adding the adjective "exalted" is unnecessary because the "unrealistic expectation" is stated as "for an elusive cure, where none exists." Exalted might be useful if the sentence did not contain "for an elusive cure, where none exists." DWC believes the adjective "exalted" is superfluous language.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Models** Medical vs. Self-Management	Commenter references the section subtitled: Medical vs. Self-Management Model, at page 5 of the Introduction. Commenter edits the last sentence of that section as follows: "This unrealistic curative view, often unwittingly fostered by healthcare providers or others, predictably leads to repeated failure, patient/client/family/ frustration, anger, delayed recovery, and unnecessary disability and costs."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The Medical vs. Self-Management Model discussion analyses the interaction between the responsibilities of the chronic pain patient and the physician in the management of the condition. The commenter's modification by inserting additional elements which result from "unrealistic curative view" such as "patient/client/family/frustration, anger," is not applicable. The meaning of the sentence is to state that unrealistic expectations will cause treatment failures, cause delays, and cause increased disability and cost. Thus, commenter's suggested modification changes the meaning of the sentence, and it is inappropriate. DWC acknowledges	None.

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			that there may be an emotional toll on all the parties; however, this is part of the delayed recovery topic. Delayed recovery is discussed elsewhere in the introduction (see section heading on subacute delayed recovery where it details how unrealistic expectations may play a role in delayed recovery and this process involves "adverse medical, familial, economic, and psychological consequences" (At p. 6.)	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Importance of early identification	Commenter references the subsection Importance of early identification, under the subtitle, Risk Stratification, at page 6 of the Introduction. Commenter edits item No. (3), and adds item No. (7) to the fourth sentence under that section as follows: Factors that help identify at-risk patients include: "(1) those unresponsive to conservative therapies demonstrated to be effective for specific diagnoses; (2) significant psychosocial factors negatively impacting recovery; (3) loss of employment or prolonged absence from ~~work~~ vocation; (4) previous history of delayed recovery or rehabilitation; (5) lack of employer support to accommodate patient needs; ~~and~~ (6) a history of childhood abuse (verbal, physical, mental); and a patient/client agenda which is return to vocation.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Vocation and work are related concepts but are not exactly synonyms in workers' compensation law. In the context of the sentence (i.e., "loss of employment or prolonged absence from work") the word absence from "work" means to be away from his or her employment where he or she is employed versus the alternate concept of being unemployed (e.g., loss of employment) and this does not relate to the concept of "vocation."	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Subacute Delayed Recovery	Commenter references the subsection Importance of early identification, under the subtitle, Risk Stratification, at page 6 of the Introduction. Commenter edits the first sentence in that section as follows: Complaints of pain are the most common obstacle to return to ~~work~~ vocation.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** See response above.	None.

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9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Subacute Delayed Recovery	Commenter references the subsection Importance of early identification, under the subtitle, Risk Stratification, at page 6 of the Introduction. Commenter edits the fourth sentence in that section as follows: When the physician recognizes that the problem is persisting beyond the anticipated time of tissue healing, the working diagnosis and treatment plan should be reconsidered, and psychosocial risk factors should be identified and addressed aggressively.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The adverb "aggressively" is not necessary as how the risk factors are to be addressed will depend on the working diagnosis, treatment plan and the nature of the psychosocial risk factors. The intensity which the psychosocial risk factor needs to be addressed will vary and will not always be aggressively addressed.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Subacute Delayed Recovery	Commenter states that the primary treating physician may appropriately address medical and psychosocial issues himself or herself, or if necessary may refer the injured employee to a multi-disciplinary program or to specialists. Commenter opines that the last sentence in the Subacute Delayed Recovery section of the Chronic Pain Medical Treatment Guidelines Introduction is not necessary and should be removed so that it does not give treating physicians the mistaken impression that they may not address the medical and psychosocial issues themselves but may only refer injured workers with subacute delayed recovery out to a multi-disciplinary program or to specialists.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree in part. Agree** that this sentence merits clarification In order to avoid confusion the sentence is modified to give the treating physician the option to refer to a multi-disciplinary program or to specialists if necessary. **Disagree** that the sentence should be deleted because it is necessary to explain that there are times where a referral is necessary.	The last sentence, under the subtitle Subacute Delayed Recovery, at page 6, is modified by adding the phrase "if necessary" at the beginning of the sentence. Thus, the last sentence, under the subtitle Subacute Delayed Recovery, as modified states: "If necessary, ~~P~~patients should be directed toward resources capable of addressing medical and psychosocial barriers to recovery."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Subacute Delayed Recovery	Commenter references the subsection Subacute Delayed Recovery, under the subtitle, Risk Stratification, at page 6 of the Introduction. Commenter edits the last sentence in that section as follows: Patients should be vigorously directed toward resources capable of addressing medical and psychosocial barriers to recovery.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The intensity in which patients will be directed toward resources capable of addressing medical and psychosocial barriers to recovery will vary and will not always be vigorous. This will be on a case by case basis at the discretion of the physician.	None.

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9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Patients with Intractable Pain	Commenter references the subsection Patients with Intractable Pain, under the subtitle, Risk Stratification, at page 6 of the Introduction. Commenter edits the first sentence of the first paragraph in that section as follows: Studies have shown that the longer a patient remains out of ~~work~~ vocational experience the less likely he/she is to return to an active vocation.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The terms "vocation" and "work" are not interchangeable terms in the workers' compensation system in the State of California. An employee may be working at a job which may not be associated with what he has been trained to do as a vocation. "Return to work" and "vocational rehabilitation" are two separate and distinct benefits under workers' compensation benefits in the State of California. Thus, commenter's edits are not accepted.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Patients with Intractable Pain	Commenter references the subsection Patients with Intractable Pain, under the subtitle, Risk Stratification, at page 6 of the Introduction. Commenter edits the last sentence of the first paragraph in that section as follows: "Nevertheless, if a patient is prepared to ~~make the~~ committed to an ongoing effort, an evaluation for admission for treatment in a multidisciplinary treatment program should be considered."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC does not find it necessary to edit the referenced sentence as suggested by the commenter. The treating physician can only require that the patient make an effort to participate in the multidisciplinary treatment program. The patient can neither be forced to participate nor can be demanded to be "committed to an ongoing effort" to participate. Thus, commenter's edits are not accepted.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Risk Stratification** Patients with Intractable Pain	Commenter references the subsection Patients with Intractable Pain, under the subtitle, Risk Stratification, at page 6 of the Introduction. Commenter edits the first sentence of the second paragraph at page 7 in that section as follows: A patient ~~suffering from~~ experiencing severe intractable pain who does not qualify for participation in a chronic pain program or who has failed a chronic pain program "should have access to proper treatment of his or her pain." California Health and Safety Code section 124960	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The language used in this sentence is language used from a California statute. (See, California Health and Safety Code section 124960.)	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Assessment Approaches** History and Physical Examination	Commenter references the subsection History and Physical Examination, under the subtitle, Assessment Approaches, at page 7 of the Introduction. Commenter edits the first sentence of the first paragraph in that section as follows: Thorough history taking is ~~always important~~ mandatory in clinical assessment and treatment planning for the patient with chronic pain.	Robert L. Barkin, PharmD, M.B.A.	**Disagree**. The requirement of making the thorough history taking "mandatory" as opposed to stating it is "important" infringes upon the doctor's medical judgment and discretion.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Assessment Approaches** History and Physical Examination	Commenter references the subsection History and Physical Examination, under the subtitle, Assessment Approaches, at page 7 of the Introduction. Commenter edits the last sentence of the first paragraph in that section as follows: Diagnostic studies and laboratories should be ordered in this context and not simply for screening purposes..	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Diagnostic studies includes laboratories, thus commenter's languages is redundant.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Assessment Approaches** History and Physical Examination	Commenter references the subsection History and Physical Examination, under the subtitle, Assessment Approaches, at page 7 of the Introduction. Commenter edits the last sentence of the second paragraph in that section as follows: Effective treatment of the chronic pain patient requires familiarity with patient-specific past diagnoses, treatment failures/successes, persistent complaints and confounding psychosocial variables (e.g. history of abuse, anxiety, depression, fear-based avoidance of activity, catastrophizing, self-medication with alcohol or prescribed or non-prescribed other drugs, patient/family expectations, medical-legal/claims management issues, and employer/supervisor/worksite).	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** "Self-medication with other alcohol or other drugs" refers to the use of agents without medical supervision whether the "other drugs" are prescribed or non-prescribed. Thus, commenter's edits are redundant.	None.
9792.24.2(a) Chronic Pain	Commenter references the subsection History and Physical Examination, under the subtitle, Assessment	Robert L. Barkin, PharmD, M.B.A.	**Disagree**. Commenter's edits are not necessary as these tests are part	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines **Part I: Introduction Assessment Approaches** History and Physical Examination	Approaches, at page 7 of the Introduction. Commenter edits the last paragraph in that section as follows: A thorough physical examination is also important for establishing reassurance and patient confidence, establishing/confirming diagnoses, and observing/understanding pain behaviors, which includes a complete metabolic profile and comprehensive urine drug testing.		of diagnostic studies which are discussed in another sentence in the first paragraph.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Functional Restoration Approach to Chronic Pain Management**	Commenter references the subsection Functional Restoration Approach to Chronic Pain Management, at page 8 of the Introduction. Commenter edits the fifth sentence of the fifth paragraph as follows: There are no ~~drugs~~ pharmacotherapies that have been proven to reverse, cure, or "heal" chronic pain or neuropathic.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Although the terms are interchangeable, the term "drugs" is more commonly used and understood by the regulated public.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Conclusion**	Commenter references the section subtitled "Conclusion" of the Introduction of the Chronic Pain Medical Treatment Guidelines at page 9. Commenter adds a sentence at the end of the conclusion which states: "This whole process is patient specific/centered."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's added sentence is superfluous. Commenter does not offer an explanation as to the value of the sentence in relation to the Chronic Pain Medical Treatment Guidelines regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Acetaminophen***	Commenter references the ***Acetaminophen*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits this guideline by adding the acronym "(APAP)" next to the word "Acetaminophen," which represents the title name of the guideline.	Robert L. Barkin, PharmD, M.B.A.	**Agree.** The individual treatment topic of Acetaminophen of the Chronic Pain Medical Treatment Guidelines has been updated pursuant to the updated version of the ODG Guidelines dated October 23, 2008 to reflect the acronym "(APAP)" after the guideline. Moreover, ODG has updated its	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Acetaminophen***, has been amended as follows: "**Acetaminophen (APAP)**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Acetaminophen (APAP) individual treatment guideline topic to thoroughly conduct an evidence-based review to incorporate the latest research on acetaminophen and NSAIDs. This has resulted in ODG revising its Acetaminophen (APAP) guideline. DWC is incorporating this guideline into its revised adapted version.	"~~See Medications for Acute Pain~~ Recommended as an initial choice for treatment of chronic pain & acute exacerbations of chronic pain. A Cochrane review of the literature on drug relief for low back pain (LBP) suggests that the popular nonsteroidal anti-inflammatory drugs (NSAIDs) are no more effective than acetaminophen, but NSAIDs had more adverse effects than acetaminophen. The results of this study support recommending NSAIDs as a treatment option after acetaminophen. (Roelofs-*Cochrane*, 2008) See NSAIDs. Long-term administration of moderate to high doses of acetaminophen should not be considered safer than NSAIDs from the perspective of the risk for developing hypertension or kidney failure. In addition this drug is one of the most common causes of severe drug-induced liver injury. Risk factors include supratherapeutic doses (> 4g a day), and use in patients with a history chronic alcohol ingestion. (Laine,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				2007) These ODG recommendations are contrary to the recently released update to the ACOEM Practice Guidelines, which say NSAIDs are recommended for treatment over acetaminophen, and they conclude that acetaminophen is modestly less efficacious. (ACOEM, 2008) But an independent review of these guidelines utilizing the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument concluded that they scored below 30% with a recommendation from AGREE, "not recommended or suitable for use in practice." (Manchikanti, 2008) (Manchikanti2, 2008)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Actiq®***	Commenter references the ***Actiq®*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Not recommended for musculoskeletal pain. Actiq® (oral transmucosal fentanyl citrate), a fast-acting highly reinforcing addictive oral transmucosal "lollipop" fentanyl analgesic ~~painkiller~~, is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Note has a	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** DWC **agrees** and ODG has accepted commenter's suggested clarification to include the "black box" warning for this medication. The revised adapted version of ODG, dated October 23, 2008, reflects that ODG has accepted portions of the comment.	The individual treatment guideline for **Actiq®** is modified as follows: **"Actiq®** (fentanyl lollipop) Not recommended for musculoskeletal pain. Actiq® (oral transmucosal fentanyl citrate), a fast-acting highly ~~addictive~~ potent "lollipop" painkiller produced by Cephalon, is

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	black box warning for abuse potential and contraindicated in acute pain; not for use in chronic pain. See Opioids."			indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Actiq is contraindicated in acute pain; it is not for use in chronic pain; and it has a Black Box warning for abuse potential. See Opioids."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Actiq®***	Commenter recommends striking all language after "Not recommended for musculoskeletal pain." Commenter believes that the document can be cited as reference, but it is much more valuable as a utilization review tool for this to be concise.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** Labor Code section 4600(a) provides, in pertinent part, that the injured worker is entitled to medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury. Labor Code section 4600(b) provides, in relevant part, that the medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the guidelines adopted by the Administrative Director pursuant to section 5307.27. Labor Code section 5307.27 provides, in part, that the medical treatment utilization schedule shall incorporate evidence-based, peer-reviewed, nationally recognized standards of care that address, at a minimum, the frequency, duration, intensity, and appropriateness of all	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			treatment procedures and modalities commonly performed in workers' compensation cases. Commenter proposes to strike all language after the recommendation in the guideline. Commenter believes that this makes the guideline a more effective utilization review tool. DWC **disagrees**. A guideline, in order to be complete, must contain not only the recommendation, but it must also contain how it is to be used, its indications, how often it is to be used, how long it is to be used, and the supporting evidence. These are the requirements of the statutes as set forth above. Although utilization review is one application, there are other applications. For example, the MTUS provides guidance to physicians as to appropriate treatment to injured workers and provides a dispute resolution system for provision of treatment outside of the MTUS.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antidepressants for chronic pain***	Commenter recommends striking all language after the first sentence, "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain, with duration of about 4-6 weeks required to effectively measure treatment outcome." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antidepressants for chronic pain [low back pain]***	Commenter makes reference to proposed section 9792.24.2(d), which states that "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline shall apply." Commenter agrees with the intent of the proposed regulations to address conflict with body part chapters in the MTUS by deferring to the relevant body part chapter to avoid contradictory advice. Commenter opines that this is an excellent concept and should avoid confusion and disputes. Commenter opines that this should be applied to antidepressants medications for low back pain by deleting this topic from the chronic pain medical treatment guidelines.	Jeffrey S. Harris, M.D. August 11, 2008	**Agree in part. Agree** that proposed section 9792.24.2(d) is intended to avoid internal conflict in the MTUS, "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline" applies. **Disagree** with commenter's analysis regarding antidepressant medications for low back pain. At the outset, the chronic pain medical treatment guidelines do not contain such an individual treatment guideline. After the condition has been determined to be chronic and the injured worker is receiving treatment under the chronic pain medical treatment guidelines, it is appropriate for that injured worker to continue to receive treatment under that guideline, including "antidepressants for chronic pain" which are available under the chronic pain guidelines. This avoids internal conflict in the MTUS and ensures provision of continuous effective medical treatment without interruption.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and	Commenter references the ***Antidepressants for neuropathic pain*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the last sentence in the treatment guideline as follows:	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** The revised adapted version of ODG, dated October 23, 2008, reflects that ODG has accepted portions of the comment. Moreover, ODG has reorganized this section removing	The individual treatment guideline for ***Antidepressants for neuropathic pain*** has been renamed **Antidepressants for chronic pain** and

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments ***Antidepressants for neuropathic pain***	"Using the data presented by Finnerup and Sindrup, a better alternative choice may be a SNRI (duloxetine, venlafaxine, desvenlafaxine) or Bupropion."		the original individual treatment topic called "antidepressants for neuropathic pain" and it is now covered under a revised section entitled "antidepressants for chronic pain." Moreover, ODG did not include "desvenlafaxine" because it is a new drug released to the U.S. market in 2008 and it has not yet being studied for off-label use in ODG's evidence review.	modified at, the second paragraph, in relevant part as follows: ***"Specifically studied underlying pain etiologies:*** (also see below for specific drugs) *Neuropathic pain:* Recommended (tricyclic antidepressants) as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. (Saarto-Cochrane, 2007) (ICSI, 2007) Other recent reviews recommended both tricyclic antidepressants and SNRIs (i.e. duloxetine and venlafaxine) as first line options. (Dworkin, 2007) (Finnerup, 2007)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antidepressants for neuropathic pain***	Commenter recommends striking all language after the first sentence, "Recommended as a first-line option for neuropathic pain." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director, Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and	Commenter references the ***Antidepressants for non-neuropathic pain*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the last two sentences in the treatment guideline as follows:	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** The revised adapted version of ODG, dated October 23, 2008, reflects that ODG has accepted portions of the comment. Moreover, ODG has reorganized this section removing	The individual treatment guideline for ***Antidepressants for non-neuropathic pain*** is re-named ***Antidepressants for chronic pain***, and modified

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments ***Antidepressants for non-neuropathic pain***	"In guidelines recommended by Perrot it was suggested that antidepressants may be prescribed as analgesics in non-depressed patients, with the ~~first-line~~ initial choice being tricyclics initiated in well selected patients (see CV, neuro, and S/E cautions) at a low dose, increasing judiciously to a maximally tolerated dose. They also suggested that trials of newer classes of antidepressants (SNRI) ~~should only be initiated if tricyclics proved to be ineffective,~~ if the patient was unable to tolerate side effects, had hard-drug interactions or they were contraindicated.		the original individual treatment topic called "antidepressants for non-neuropathic pain" and it is now covered under a revised section entitled "antidepressants for chronic pain." Commenter's suggested changes pertain to mostly precautions in using certain antidepressants. In the revised section, ODG covers precautions extensively for specific drug classes.	at page 13, third paragraph and pertinent portion of the last paragraph of the guideline, in relevant part, as follows: *"Non-neuropathic pain:* Recommended as an option in depressed patients, but effectiveness is limited. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. In guidelines for painful rheumatic conditions recommended by Perrot, it was suggested that antidepressants may be prescribed as analgesics in non-depressed patients, with the first-line choice being tricyclics initiated at a low dose, increasing to a maximally tolerated dose. (Perrot, 2006)" **"SPECIFIC ANTIDEPRESSANTS:** ***Tricyclic antidepressants*** are recommended over selective serotonin reuptake inhibitors (SSRIs), unless adverse reactions are a problem. Caution is required because tricyclics have a low threshold for toxicity, and tricyclic antidepressant overdose is a significant

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				cause of fatal drug poisoning due to their cardiovascular and neurological effects. …"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antidepressants for neuropathic pain***	Commenter recommends striking all language after the first sentence, "Recommended as a first-line option for neuropathic pain." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)[for low back pain]***	Commenter makes reference to proposed section 9792.24.2(d), which states that "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline shall apply." Commenter agrees with the intent of the proposed regulations to address conflict with body part chapters in the MTUS by deferring to the relevant body part chapter to avoid contradictory advice. Commenter opines that this is an excellent concept and should avoid confusion and disputes. Commenter opines that this should be applied to antiepilepsy medications for low back pain by deleting this topic from the chronic pain medical treatment guidelines.	Jeffrey S. Harris, M.D. August 11, 2008	**Agree in part. Agree** that proposed section 9792.24.2(d) is intended to avoid internal conflict in the MTUS. This section provides that "when the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline shall apply." **Disagree** with commenter's analysis regarding antiepilepsy medications for low back pain. At the outset, the chronic pain medical treatment guidelines do not contain such an individual treatment guideline. After the condition has been determined to be chronic and the injured worker is receiving treatment under the chronic pain medical treatment guidelines, it is appropriate for that injured worker to continue to receive treatment	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			under that guideline, including "antiepilepsy drugs (AEDs)" which are available under the chronic pain guidelines. This avoids internal conflict in the MTUS and ensures provision of continuous effective medical treatment without interruption.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 14, 2nd full paragraph, as follows: "Painful polyneuropathy: AEDs are recommended on a trial basis (gabapentin)~~/pregabalin)~~ outcome 30% better than placebo as a first-line therapy for painful polyneuropathy (with diabetic polyneuropathy being the most common example). The other first-line options are a tri-cyclic antidepressant (if tolerated by the patient), or a SNRI antidepressant (such as duloxetine, venlafaxine, desuenlafaxine). (Attal, 2006) (Jensen, 2006) Postherpetic neuralgia: Gabapentin and pregabalin are recommended. (Attal, 2006) (Backonja, 2004)"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Recommended for neuropathic pain (pain due to nerve damage), but not for acute somatic pain." Specifically studied disease states: (also see below for specific drugs)	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Painful polyneuropathy: AEDs are recommended on a trial basis (gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy (with diabetic polyneuropathy being the most common example). Central pain: There are so few trials (with such small sample size) that treatment is generally based on that recommended for peripheral neuropathy, with gabapentin and pregabalin recommended. Acute pain: Not indicated due to lack of evidence. Chronic non-specific axial low back pain: There is no evidence to support the use of these medications for this indication. Treatment of pain associated with osteoarthritis of the hip: Not indicated Spinal cord injury: Gabapentin is recommended for chronic neuropathic pain. CRPS: Gabapentin has been recommended Fibromyalgia: Gabapentin and pregabalin have been found to be safe and efficacious to treat pain and other symptoms. (Arnold, 2007) (Crofford, 2005) Pregabalin is FDA approved for fibromyalgia. Lumbar spinal stenosis: Gabapentin produced statistically significant improvement in walking distance, decrease in pain with movement and sensory deficit in a pilot study. Myofascial pain: Not recommended Postop pain: AEDs may also be an option for postoperative pain, resulting in decreased opioid			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	consumption.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 14, 9th full paragraph, as follows: "Fibromyalgia: Gabapentin and pregabalin have been found to be safe and efficacious to treat FMS pain and other symptoms. (Arnold, 2007) (Crofford, 2005) Pregabalin is FDA approved for fibromyalgia.(20 – 30% better than placebo)."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline at page 14, 12th full paragraph, as follows: "Postop pain: AEDs may also be an option for postoperative pain, resulting in modest decreased opioid consumption. (Peng, 2007) (Buvanendran, 2007)"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline at page 15, 5th full paragraph, as follows: "Side-Effect Profile: Gabapentin has a somewhat favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline at page 15, 6th full paragraph, as follows: "Postherpetic neuralgia – Starting regimen of 300 mg once daily on Day 1, then increase to 300 mg twice daily on Day 2; then increase to 300 mg three times daily on Day 3. Dosage may be increased as needed up to a total daily dosage of 1800 mg in three divided doses <u>based on tolerability and expected pain relief</u>. Doses above 1800 mg/day have not demonstrated an additional benefit in clinical studies. (Neurontin package insert.)"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline at page 16, 1st full paragraph, as follows: "Diabetic neuropathy (off-label indication) – Gabapentin dosages range from 900 mg to 3600 mg in three divided doses (Backonja, 2002) (Eisenberg,	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	2007). Gabapentin is 100% renally excreted. (Caution with creatinine clearance less than or equal to 60 ml/min.)"			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 16, 2nd full paragraph, as follows: "Recommended Trial Period: One recommendation for an adequate trial with gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug with a different mechanism of action is recommended. Combination therapy is only recommended if there is no change with first-line therapy, with the recommended change being at least 30%. (TCA, SNRI or AED). (Jensen, 2006) (Eisenberg, 2007)"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 16, 3rd paragraph, as follows: "Weaning and/or changing to another drug in this class: Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert) When to switch or if to switch to pregabalin: If there	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	is evidence of inadequate response, intolerance, hypersensitivity or contraindications. There have been no head-to-head comparison trails of the two drugs."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 16, 4th full paragraph, as follows: "Pregabalin (Lyrica®) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both 30% better than placebo. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced the approval of pregabalin as the first approved treatment for fibromyalgia. (ICSI, 2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) Dose adjustment is necessary in patients with renal insufficiency. (creatinine clearance less than or equal to 60 ml/min) Perform baseline creatine clearance Ccr. Side-Effect Profile: Pregabalin has been associated with many side effects including peripheral edema, CNS depression, weight gain, QTC prolongation, thrombocytopenia, cognitive changes, euphoria, asthenia, amnesia, confusion and blurred vision. Somnolence and dizziness have been reported to be the most common side effects related to tolerability. (Tassone, 2007) (Attal, 2006) It has been suggested that this drug be avoided if the patient has a problem with weight gain. (Jensen, 2006) caution: elderly, renal function, congestive heart failure,	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations. For the benefit of the public the pertinent guideline related to Pregabalin (Lyrica) is set forth in the action portion of the chart.	The individual treatment guideline of ***Antiepilepsy drugs (AEDs)*** has been amended at paragraph 1, page 20, under the subtitle ***Pregabalin (Lyrica®, no generic available)***, as follows: ***"Pregabalin (Lyrica®, no generic available)*** has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced the approval of pregabalin as the first approved treatment for fibromyalgia. (ICSI, 2007) (Tassone, 2007) (Knotkova,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	depression, angioedema, suicidality."			2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008) Dose adjustment is necessary in patients with renal insufficiency. The antiepileptic agents gabapentin and pregabalin have attained widespread usage in the treatment of painful diabetic peripheral neuropathy (DPN). This pooled analysis of 7 randomized controlled trials comparing different doses and frequencies of pregabalin for painful DPN concluded that pregabalin at doses of 150, 300, and 600 mg daily is associated with dose-related relief of pain and reduction in sleep interference in patients with painful DPN. (Freeman, 2008) "*Side-Effect Profile:* Pregabalin has been associated with many side effects including edema, CNS depression, weight gain, and blurred vision. Somnolence and dizziness have been reported to be the most common side effects related to tolerability. (Tassone, 2007) (Attal, 2006) It has been suggested that this drug be avoided if the patient has a problem

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				with weight gain. (Jensen, 2006)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 16, last paragraph as follows: "Diabetic neuropathy – Begin with 50 mg 3 times a day <u>based upon creatinine clearance (renal function)</u>; may be increased in one week based on tolerability and effect to a maximum of 300 mg/day. (Doses up to 600 mg/day were evaluated with no additional benefit and increase in side effects.) "	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 17, 2nd paragraph, as follows: "Weaning: Do not discontinue pregabalin abruptly and weaning should occur over a one-week period. Withdrawal effects have been reported after abrupt discontinuation. <u>Note: 90% of drug excreted unchanged in urine (perform baseline renal function creatinine).</u>"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 17, 3rd paragraph, as follows: "Side-Effect Profile: Lamotrogine is associated with many side effects, including a life-threatening skin rash, Stevens-Johnson syndrome (incidence 1/1000),	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	and it has been reported that up to 7% developed a skin rash that may be dose-dependent. (Wiffen-Cochrane, 2007) There is a black box warning regarding skin rashes for this medication. The drug should be discontinued at first sign of rash. (Eisenberg, 2007) Other side effects include dizziness, nausea, headache and fatigue. Caution if renal function impairment lowers function [illegible]. ”			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 17, 4th paragraph, as follows: “Dosing Information (off-label indication): Begin with 25 mg daily; then titrate up by 25 mg to 50 mg every 1-2 weeks up to 400 mg/day; titration must occur slowly and tapering should occur upon discontinuation. (ICSI, 2007) May have autoinduction in metabolism.”	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG’s style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Antiepilepsy drugs (AEDs)***	Commenter references the ***Antiepilepsy drugs (AEDs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 18, last paragraph, as follows: “Topiramate (Topamax®) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of “central” etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile ~~limits its use in this regard~~ of renal stones (hydrate patients) and other dose related events require monitoring. (Rosenstock, 2007)”	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG’s style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Anti-inflammatory medications***	Commenter references the ***Anti-inflammatory medications*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, in relevant part, as follows: COX-2 inhibitors (e.g., Celebrex – a CYP 450206 inhibitor) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost. (Rate of overall GI bleeding is 3% with COX-2's versus 4.5% with ibuprofen.) (Homik, 2003) For precautions in specific patient populations, see NSAIDs, GI symptoms, renal function decrements & cardiovascular risk.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Anti-inflammatory medications***	Commenter recommends striking all language after the first two sentences, "For specific recommendations, see NSAIDs (non-steroidal anti-inflammatory drugs). Anti-inflammatories are the traditional first line treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments	Commenter references the ***Antispastic agents*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "See Muscle relaxants (none work at myoneural	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Antispastic agents	junction, asibe dantrolin)."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Barbiturate-containing analgesic agents (BCAs)***	Commenter references the ***Barbiturate-containing analgesic agents (BCAs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, in pertinent part, as follows: "Fioricet like products is commonly used for acute headache, with some limited data to support it, but there is a risk of medication overuse as well as rebound headache or pharmacologically maintained headache. (Friedman, 1987). See also Opioids."	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** ODG has revised the individual treatment guideline for Barbiturate-containing analgesic agents (BCAs). The changes reflect, in part, commenter's suggestions.	The individual treatment guideline for ***Barbiturate-containing analgesic agents (BCAs)*** is modified at page 23, as follows: "Not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. (McLean, 2000) ~~Fioricet is commonly used for acute headache, with some data to support it, but~~ ~~t~~There is a risk of medication overuse as well as rebound headache. (Friedman, 1987)~~.~~ See also Opioids".
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Barbiturate-containing analgesic agents (BCAs)***	Commenter recommends striking all language after the first sentence, "Not recommended for chronic pain." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, July 28, 2008, on individual treatment topic guideline, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment	Commenter points out that unlike the ACOEM's draft updated chapter on chronic pain, the modified ODG guidelines on chronic pain do not always meet this	Brenda Ramirez, Claims and Medical Director	**Agree.** The revised individual treatment topic guideline for ***Behavioral interventions*** has been	The individual treatment topic guideline for ***Behavioral interventions*** has

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines **Part 2.** Pain Intervention and Treatments ***Behavioral interventions***	standard of frequency, duration and intensity as required by the statute (for example *Behavioral interventions).*	California Workers' Compensation Institute August 12, 2008	revised pursuant to the revised October 23, 2008 ODG version to address commenter's concerns and is set forth in the action portion of this chart for the benefit of the public.	been revised pursuant to the revised October 23, 2008 ODG version at p. 24 as follows: **"Behavioral interventions** "Recommended. The identification and reinforcement of coping skills is often more useful in the treatment of pain than ongoing medication or therapy, which could lead to psychological or physical dependence. See also Multi-disciplinary pain programs. **"ODG Cognitive Behavioral Therapy (CBT) guidelines for chronic pain:** Screen for patients with risk factors for delayed recovery, including fear avoidance beliefs. See Fear-avoidance beliefs questionnaire (FABQ). "Initial therapy for these "at risk" patients should be physical medicine for exercise instruction, using a cognitive motivational approach to physical medicine. "Consider separate psychotherapy CBT referral after 4 weeks if lack of progress from physical

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				medicine alone: - Initial trial of 3-4 psychotherapy visits over 2 weeks - With evidence of objective functional improvement, total of up to 6-10 visits over 5-6 weeks (individual sessions)."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Benzodiazepines***	Commenter recommends striking all language after the first two sentences, "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Benzodiazepines***	Commenter references the ***Benzodiazepines*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, in relevant part, as follows: Schedule IV Controlled Substances Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety (SSRI [selective serotonin reuptake inhibitors], SNRI [serotonin-norepinephrine reuptake inhibitor]). A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Some patients experience disinhibitive and amnestic effects. (Baillargeon, 2003) (Ashton, 2005)	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Biofeedback***	Commenter recommends striking all language after the first sentence, "Not recommended as a stand-alone treatment, but recommended as an option in a cognitive behavioral therapy (CBT) program to facilitate exercise therapy and return to activity." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director Anthem Blue Cross July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Boswellia Serrata Resin (Frankincense) [DWC]***	Commenter agrees with guideline.	Theodore Blatt, M.D. Medical Director Anthem Blue Cross July 28, 2008	**Agree.**	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Botulinum toxin (Botox)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Not recommended for chronic pain disorders, but recommended for cervical dystonia." *"Not recommended for the following: headache; fibromyositis; chronic low back pain; chronic neck pain; myofascial pain syndrome; & trigger point injections."* *"Recommended: cervical dystonia*, a condition that is not generally related to workers' compensation injuries (also known as spasmodic torticolis), and is characterized as a movement disorder of the nuchal	Theodore Blatt, M.D. Medical Director Anthem Blue Cross July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	muscles, characterized by tremor or by tonic posturing of the head in a rotated, twisted, or abnormally flexed or extended position or some combination of these positions."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Bupropion (Wellbutrin®)***	Commenter references the ***Bupropion (Wellbutrin®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "See Antidepressants for Neuropathic pain (reuptake blockade or NE [nonrepinephrine] & DA [dopamine].)"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations. The individual treatment topic guideline for Bupropion (Wellbutrin®) has been revised pursuant to the revised October 23, 2008 ODG updated version and is set forth in the action column of the chart for the benefit of the regulated public.	The individual treatment topic guideline for ***Bupropion (Wellbutrin®)*** has been revised pursuant to the revised October 23, 2008 ODG updated version as set forth below: **"Bupropion (Wellbutrin®)** Recommended as an option after other agents. While bupropion has shown some efficacy in neuropathic pain there is no evidence of efficacy in patients with non-neuropathic chronic low back pain. Furthermore, bupropion is generally a third-line medication for diabetic neuropathy and may be considered when patients have not had a response to a tricyclic or SNRI. See Antidepressants for ~~Neuropathic~~ chronic pain for general guidelines, as well as specific Bupropion listing for more information and references."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter references the ***Cannabinoids*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The referenced material does not add to the substance of the guideline. It has been forwarded to the editors of the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments ***Cannabinoids***	as follows: "At this time it is difficult to justify advising patients to smoke street-grade marijuana, presuming that they will experience benefit, when they may also be harmed. (Mackie, 2007) (Moskowitz, 2007) – See McCarbage and Barkin extensive article on this. AM J Ther 2007 (Sep-Oct; 14(5) 475-83."		ODG guidelines for their consideration as to whether it meets the criteria for inclusion in their guidelines.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Cannabinoids***	Commenter recommends striking all language after the first sentence, "Not recommended." Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Capsaicin, topical [ODG]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Recommended only as an option in patients who have not responded or are intolerant to other treatments." Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Commenter questions as to whether Capsaicin is considered a "medical treatment" as per the Labor Code or a "medical food" which is not considered a	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. Moreover, DWC modified the original ODG guidelines' topic heading to remove the individual treatment topic heading for Capsaicin, topical (chili pepper/ cayenne pepper) to better reflect the topic. The ODG guidelines text discussed the pharmaceutical formulations of capsaicin. It did not include a discussion on chili pepper or cayenne pepper. The	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	medication by the FDA? If this is not a medication, are the payors obligated to pay for something that is not a "medical treatment" as defined by the labor code? Commenter states that this is becoming a very contentious issue and that clarification of this would be incredibly useful.		topic heading was changed to delete the references to chili pepper and cayenne pepper to better reflect the substance of the guidelines text. However, the ODG individual treatment topic was not changed and an evidence-based review was not conducted. Capsaicin is a drug in its purified form. Thus commenter is incorrect that Capsaicin is a medical food.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Carbamazepine (Tegretol®)***	Commenter references the ***Carbamazepine (Tegretol®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows **:** **Carbamazepine ~~(Tegretol®)~~ CBZ** See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Carbamazepine listing. A hepatic inducer; autoinhibition of CBZ metabolism.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability. Moreover, DWC **disagrees** with the remaining recommended changes as the general editing comments are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Carisoprodol (Soma®)***	Commenter references the ***Carisoprodol (Soma®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: **Carisoprodol (~~Soma®~~)** See Muscle relaxants. Avoid use.	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability. Moreover, **disagree** with the remaining recommended changes as the general editing comments are inconsistent with ODG's style and do not address the substance of the regulations. However, the individual treatment topic guideline for Carisoprodol	The individual treatment guideline for ***Carisoprodol (Soma®)*** at pp. 29-30, is modified as follows: "Not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			(Soma®) has been revised pursuant to the ODG October 23, 2008 version. It is set forth in this chart for the benefit of the regulated public.	substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a "Las Vegas Cocktail"); & (5) as a combination with codeine (referred to as "Soma Coma"). (Reeves, 1999) (Reeves, 2001) (Reeves, 2008) (Schears, 2004) There was a 300% increase in numbers of emergency room episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) Intoxication appears to

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				include subdued consciousness, decreased cognitive function, and abnormalities of the eyes, vestibular function, appearance, gait and motor function. Intoxication includes the effects of both carisoprodol and meprobamate, both of which act on different neurotransmitters. (Bramness, 2007) (Bramness, 2004) A withdrawal syndrome has been documented that consists of insomnia, vomiting, tremors, muscle twitching, anxiety, and ataxia when abrupt discontinuation of large doses occurs. This is similar to withdrawal from meprobamate. (Reeves, 2007) (Reeves, 2004) There is little research in terms of weaning of high dose carisoprodol and there is no standard treatment regimen for patients with known dependence. Most treatment includes treatment for symptomatic complaints of withdrawal. Another option is to switch to phenobarbital to prevent withdrawal with subsequent tapering. A maximum dose of

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				phenobarbital is 500 mg/day and the taper is 30 mg/day with a slower taper in an outpatient setting. Tapering should be individualized for each patient. (Boothby, 2003) For more information and references, ~~S~~see Muscle relaxants. See also Weaning of medications."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic Pain Programs***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Recommended where there is access to programs with proven successful outcomes, for patients with conditions that put them at risk of delayed recovery." Patients should also be motivated to improve and return to work, and meet the patient selection criteria outlined below. Also called Multidisciplinary pain programs or Interdisciplinary rehabilitation programs, these pain rehabilitation programs combine multiple treatments, and at the least, include psychological care along with physical therapy (including an active exercise component as opposed to passive modalities). Types of programs: There is no one universal definition of what comprises interdisciplinary/multidisciplinary treatment. The most commonly referenced programs have been defined in the following general ways: (1) Multidisciplinary programs: Involves one or two specialists directing the services of a number of team members, with these specialists often having independent goals. These programs can be further subdivided into four levels of pain programs:	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, July 28, 2008, on individual treatment topic guideline, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(a) Multidisciplinary pain centers (generally associated with academic centers and include research as part of their focus) (b) Multidisciplinary pain clinics (c) Pain clinics (d) Modality-oriented clinics (2) Interdisciplinary pain programs: Involves a team approach that is outcome focused and coordinated and offers goal-oriented interdisciplinary services. Communication on a minimum of a weekly basis is emphasized. The most intensive of these programs is referred to as a Functional Restoration Program, with a major emphasis on maximizing function versus minimizing pain. See Functional restoration programs. Types of treatment: Components suggested for interdisciplinary care include the following services delivered in an integrated fashion: (a) physical treatment; (b) medical care and supervision; (c) psychological and behavioral care; (d) psychosocial care; (e) vocational rehabilitation and training; and (f) education. Criteria for the general use of multidisciplinary pain management programs: Outpatient pain rehabilitation programs may be considered medically necessary when all of the following criteria are met: (1) An adequate and thorough evaluation has been made, including baseline functional testing so follow-up with the same test can note functional improvement; (2) Previous methods of treating the chronic pain have been unsuccessful; (3) The patient has a significant loss of ability to function independently resulting from the chronic pain; (4) The patient is not a candidate where surgery would clearly			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	be warranted; (5) The patient exhibits motivation to change, and is willing to forgo secondary gains, including disability payments to effect this change; & (6) Negative predictors of success above have been addressed. Integrative summary reports that include treatment goals, progress assessment and stage of treatment, must be made available upon request and at least on a bi-weekly basis during the course of the treatment program. Treatment is not suggested for longer than 2 weeks without evidence of demonstrated efficacy as documented by subjective and objective gains. Inpatient pain rehabilitation programs: These programs typically consist of more intensive functional rehabilitation and medical care than their outpatient counterparts. They may be appropriate for patients who: (1) don't have the minimal functional capacity to participate effectively in an outpatient program; (2) have medical conditions that require more intensive oversight; (3) are receiving large amounts of medications necessitating medication weaning or detoxification; or (4) have complex medical or psychological diagnosis that benefit from more intensive observation and/or additional consultation during the rehabilitation process. As with outpatient pain rehabilitation programs, the most effective programs combine intensive, daily biopsychosocial rehabilitation with a functional restoration approach.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and	Commenter specifically requests that the following paragraph not be included in this section: "Predictors of success and failure: As noted, one of the criticisms of interdisciplinary/multidisciplinary rehabilitation programs is the lack of an appropriate	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments ***Chronic Pain Programs***	screening tool to help to determine who will most benefit from this treatment. Retrospective research has examined decreased rates of completion of functional restoration programs, and there is ongoing research to evaluate screening tools prior to entry. (Gatchel, 2006) The following variables have been found to be negative predictors of efficacy of treatment with the programs as well as negative predictors of completion of the programs: (1) a negative relationship with the employer/supervisor; (2) poor work adjustment and satisfaction; (3) a negative outlook about future employment; (4) high levels of psychosocial distress (higher pretreatment levels of depression, pain and disability); (5) involvement in financial disability disputes; (6) greater rates of smoking; (7) duration of pre-referral disability time; (8) prevalence of opioid use; and (9) pre-treatment levels of pain." Commenter states that while this information is important as a reference piece, it is too controversial and subjective to put in the MTUS. Commenter states that from a user perspective that many payors are likely going to provide information that is very subjective "hearsay" which should not be part of a utilization review decision. Commenter feels that keeping this paragraph in the MTUS will open this door.		Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Clonidine, Intrathecal [DWC]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Recommended. The evidence supports the use of intrathecal clonidine alone or in conjunction with opioids (e.g., morphine) and local anesthetics (e.g., bupivicaine) in the treatment of Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

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	(CRPS/RSD). Intrathecal clonidine can also be used in conjunction with opioids for neuropathic pain." Commenter questions the meaning of the following sentence in the guideline: "There is no evidence that intrathecal clonidine alone is effective in the treatment of pain after spinal cord surgery." Commenter questions if this means that it is not indicated in patients with pain following spinal surgery such as fusion, discectomy etc.??? If so, commenter opines that the DWC needs to specifically state that. If it means surgery to the spinal cord (i.e., tumor resection), then this needs to be clarified.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic pain programs***	Commenter states that in his work with Interdisciplinary Pain Rehabilitation Program evaluations, he finds that nearly 40% of patients are not ready for rehabilitation. Commenter states that the peer review literature speaks to this issue by commenting upon readiness for change. Commenter states that this issue is alluded to in the guideline section referring to chronic pain programs. Commenter refers to the chronic pain programs treatment guideline at p. 23, first paragraph, and quotes the following: "While recommended, the research remains ongoing as to (1) what is considered the "gold-standard" content for treatment; (2) the group of patients that benefit most from this treatment; (3) the ideal timing of when to initiate treatment; (4) the intensity necessary for effective treatment; and (5) cost-effectiveness." Commenter states that the guideline speaks to the issue of staging progress but then remains silent on how that staging may determine readiness for any particular treatment. Commenter makes reference to researchers Prochaska	William G. Brose, M.D. Health Education for Living with Pain, August 8, 2008	**Agree in part.** DWC **agrees** with the comment regarding the timing of reporting of initial progress made to substantiate continued participation in the chronic pain program. ODG has revised the individual treatment topic guideline for chronic pain programs, in its October 23, 2008 version, to better monitor the initial progress in order to support continued treatment in the program. Moreover, there is a subset of patients where the goal of the chronic pain program is to help the patient avoid certain types of elective surgeries. For these cases, monitoring the initial response to treatment in the chronic pain program may be important in that	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2., Pain Intervention and Treatments, ***Chronic pain programs***, has been revised as follows: **"Chronic pain programs (functional restoration programs)** Recommended where there is access to programs with proven successful outcomes, for patients with conditions that put them at risk of delayed recovery. Patients should also be motivated to improve and return to work, and meet the patient selection criteria outlined

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	and DiClemente, who published on the topic of the transtheoretical model of change. Commenter states that this model is well applied to chronic pain patients within the workers' compensation system in that identification of a patient's stage may be a predictor of their readiness to change to identify the optimal timing of resources. Commenter references the ***Chronic pain programs*** treatment guideline at page 24: "Integrative summary reports that include treatment goals, progress assessment and stage of treatment, must be made available upon request and at least on a bi-weekly basis during the course of the treatment program. Treatment is not suggested for longer than 2 weeks without evidence of demonstrated efficacy as documented by subjective and objective gains." Commenter states the initial 2 weeks of Interdisciplinary Pain Rehabilitation Program treatment will be facilitated but in the event of a patient's stage of readiness for change not being achieved that patient will predictably find it difficult to receive additional treatment due to lack of documented functional progress. Commenter states that often this circumstance is due to the patient being at the precontemplative or contemplative stage of a change process rather than at the preparation or action stage. Commenter states that while ongoing research will need to be performed to develop optimal timing of treatment events, the need to treat as described above will not find a facilitated process unless the guidelines are amended to prevent obstruction of treatment by misguided review. Commenter believes that this can be best addressed by adding to the introduction section of the guideline on page 9: *Subsequent treatment under the guideline*		if a determination is made that the patient is not benefiting from the program, the program should be discontinued, and surgical alternative should be pursued. Further, the guideline has been revised to suggest that a continuous course of treatment should not be interrupted at two weeks solely to document these gains, if there are preliminary indications that these gains are being made on a concurrent basis. **Disagree** with comment that patients with bilingual, bicultural needs require more time as commenter provides no evidence-base to support his allegations.	below. Also called Multidisciplinary pain programs or Interdisciplinary rehabilitation programs, these pain rehabilitation programs combine multiple treatments, and at the least, include psychological care along with physical therapy & occupational therapy (including an active exercise component as opposed to passive modalities). While recommended, the research remains ongoing as to (1) what is considered the "gold-standard" content for treatment; (2) the group of patients that benefit most from this treatment; (3) the ideal timing of when to initiate treatment; (4) the intensity necessary for effective treatment; and (5) cost-effectiveness. It has been suggested that interdisciplinary/multidisciplinary care models for treatment of chronic pain may be the most effective way to treat this condition. (Flor, 1992) (Gallagher, 1999) (Guzman, 2001) (Gross, 2005) (Sullivan, 2005) (Dysvik, 2005) (Airaksinen, 2006) (Schonstein, 2003) (Sanders, 2005) (Patrick, 2004)

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	needs to be provided with concurrent monitoring of their functional progress, or other measurement of change, that would predict the opportunity for a reduction in the impact of the industrial injury over a specified measurement interval. Commenter opines that in this way the individual patient's progress and measurement of change is the determinant of resources being provided rather than population based evidence which could lead to earlier application of the very same resources only to achieve a less optimal outcome. Commenter opines that such a modification in the outline and a statement supporting the presumptive authority of that introduction section for purposes of determining treatment authorization would allow for the continued care mandated by the guideline and the Labor Code, and the California Health and Safety Code, while creating a method for continued measurement and monitoring of functional progress in accordance with the stages that it infers. Commenter also requests a modification in the standard of measurement for Latino patients as a special need group who are currently underserved. Commenter states that this group is well recognized as the fastest growing segment of California population and yet their access to interdisciplinary services is inadequate at present. Commenter states that with growth far outpacing those resources, this group will only become less well served in the foreseeable future. Commenter indicates that the evidence that was used to formulate the guidelines was not evidence unique to the Latino community. Commenter indicates that in fact their need for bilingual, bicultural services is not even addressed in the document. Commenter opines that as a consequence, the lower educational level of these patients, the greater resource investment necessary to treat them and the unique cultural perspective necessary to facilitate their			(Buchner, 2006) Unfortunately, being a claimant may be a predictor of poor long-term outcomes. (Robinson, 2004) These treatment modalities are based on the biopsychosocial model, one that views pain and disability in terms of the interaction between physiological, psychological and social factors. (Gatchel, 2005) There appears to be little scientific evidence for the effectiveness of multidisciplinary biopsychosocial rehabilitation compared with other rehabilitation facilities for neck and shoulder pain, as opposed to low back pain and generalized pain syndromes. (Karjalainen, 2003) ***"Types of programs:*** There is no one universal definition of what comprises interdisciplinary/multidisciplinary treatment. The most commonly referenced programs have been defined in the following general ways (Stanos, 2006): (1) Multidisciplinary programs: Involves one or two specialists directing the services of a number of team members, with these

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	demonstration of functional change have not been considered. Commenter adds that the result is an unintended but unfortunate bias that needs to be addressed. Commenter states that the need to provide culturally sensitive and specific treatment to these patients needs to be recognized. Commenter states that his experience as a provider of those specialty bilingual, bicultural Latino services has revealed that 6 weeks of time in an IPRP are frequently required to achieve functional progress. Commenter states that the patients require a more extensive exposure to treatment resources related to their unique educational and cultural needs. Commenter requests that for this special group of injured workers with chronic pain who are non-English speaking that their treatment in an IPRP be supported for 4-6 weeks to demonstrate the evidence of functional progress called for in the draft guideline.			specialists often having independent goals. These programs can be further subdivided into four levels of pain programs: (a) Multidisciplinary pain centers (generally associated with academic centers and include research as part of their focus) (b) Multidisciplinary pain clinics (c) Pain clinics (d) Modality-oriented clinics (2) Interdisciplinary pain programs: Involves a team approach that is outcome focused and coordinated and offers goal-oriented interdisciplinary services. Communication on a minimum of a weekly basis is emphasized. The most intensive of these programs is referred to as a Functional Restoration Program, with a major emphasis on maximizing function versus minimizing pain. See Functional restoration programs. ***"Types of treatment:*** Components suggested for interdisciplinary care include the following services delivered in an integrated fashion: (a) physical treatment; (b) medical care

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				and supervision; (c) psychological and behavioral care; (d) psychosocial care; (e) vocational rehabilitation and training; and (f) education. ***"Predictors of success and failure:*** As noted, one of the criticisms of interdisciplinary/multidisciplinary rehabilitation programs is the lack of an appropriate screening tool to help to determine who will most benefit from this treatment. Retrospective research has examined decreased rates of completion of functional restoration programs, and there is ongoing research to evaluate screening tools prior to entry. (Gatchel, 2006) The following variables have been found to be negative predictors of efficacy of treatment with the programs as well as negative predictors of completion of the programs: (1) a negative relationship with the employer/supervisor; (2) poor work adjustment and satisfaction; (3) a negative outlook about future employment; (4) high levels of psychosocial distress

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				(higher pretreatment levels of depression, pain and disability); (5) involvement in financial disability disputes; (6) greater rates of smoking; (7) duration of pre-referral disability time; (8) prevalence of opioid use; and (9) pre-treatment levels of pain. (Linton, 2001) (Bendix, 1998) (McGeary, 2006) (McGeary, 2004) (Gatchel, 2005) Multidisciplinary treatment strategies are effective for patients with chronic low back pain (CLBP) in all stages of chronicity and should not only be given to those with lower grades of CLBP, according to the results of a prospective longitudinal clinical study reported in the December 15 issue of Spine. (Buchner, 2007) See also Chronic pain programs, early intervention; Chronic pain programs, intensity; Chronic pain programs, opioids; and Functional restoration programs. **"Criteria for the general use of multidisciplinary pain management programs:** "Outpatient pain

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				rehabilitation programs may be considered medically necessary when all of the following criteria are met: (1) An adequate and thorough evaluation has been made, including baseline functional testing so follow-up with the same test can note functional improvement; (2) Previous methods of treating the chronic pain have been unsuccessful and there is an absence of other options likely to result in significant clinical improvement; (3) The patient has a significant loss of ability to function independently resulting from the chronic pain; (4) The patient is not a candidate where surgery or other treatments would clearly be warranted (if a goal of treatment is to prevent or avoid controversial or optional surgery, a trial of 10 visits may be implemented to assess whether surgery may be avoided); (5) The patient exhibits motivation to change, and is willing to forgo secondary gains, including disability payments to effect this change; & (6) Negative predictors of success above

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				have been addressed. Integrative summary reports that include treatment goals, progress assessment and stage of treatment, must be made available upon request and at least on a bi-weekly basis during the course of the treatment program. Treatment is not suggested for longer than 2 weeks without evidence of demonstrated efficacy as documented by subjective and objective gains. (Note: Patients may get worse before they get better. For example, objective gains may be moving joints that are stiff from lack of use, resulting in increased subjective pain.) However, it is also not suggested that a continuous course of treatment be interrupted at two weeks solely to document these gains, if there are preliminary indications that these gains are being made on a concurrent basis. Total treatment duration should generally not exceed 20 full-day sessions (or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities).

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				(Sanders, 2005) Treatment duration in excess of 20 sessions requires a clear rationale for the specified extension and reasonable goals to be achieved. Longer durations require individualized care plans and proven outcomes, and should be based on chronicity of disability and other known risk factors for loss of function. "Inpatient pain rehabilitation programs: These programs typically consist of more intensive functional rehabilitation and medical care than their outpatient counterparts. They may be appropriate for patients who: (1) don't have the minimal functional capacity to participate effectively in an outpatient program; (2) have medical conditions that require more intensive oversight; (3) are receiving large amounts of medications necessitating medication weaning or detoxification; or (4) have complex medical or psychological diagnosis that benefit from more intensive observation and/or additional consultation during the

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				rehabilitation process. (Keel, 1998) (Kool, 2005) (Buchner, 2006) (Kool, 2007) As with outpatient pain rehabilitation programs, the most effective programs combine intensive, daily biopsychosocial rehabilitation with a functional restoration approach. (BlueCross BlueShield, 2004) (Aetna, 2006) See Functional restoration programs **"Chronic pain programs, early intervention** "Recommended depending on identification of patients that may benefit from early intervention via a multidisciplinary approach, as indicated below. The likelihood of return to work diminishes significantly after approximately 3 months of sick leave. It is now being suggested that there is a place for interdisciplinary programs at a stage in treatment prior to the development of permanent disability, and this may be at a period of no later than 3 to 6 months after a disabling injury. (Robinson, 2004) (Gatchel, 2003) This early

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				intervention has been referred to as "secondary treatment," and differs from the more traditional, palliative care pain programs by not only the earlier onset of treatment, but by treatment intensity and level of medical supervision. (Mayer 2003) Multidisciplinary treatment strategies are effective for patients with chronic low back pain (CLBP) in all stages of chronicity and should not only be given to those with lower grades of CLBP, according to the results of a prospective longitudinal clinical study reported in the December 15 issue of Spine. (Buchner, 2007) This study to evaluate RTW outcomes following proactive, combined clinical, occupational and case management-based interdisciplinary early intervention, provided in a workers' compensation environment at 4-10 weeks of onset of back pain, concluded that multimodal early intervention was more effective for workers with sub-acute back pain who are at high risk of occupational disability. (Schultz, 2008)

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				Recommendations for identification of patients that may benefit from early intervention via a multidisciplinary approach: (a) The patient's response to treatment falls outside of the established norms for their specific diagnosis without a physical explanation to explain symptom severity. (b) The patient exhibits excessive pain behavior and/or complaints compared to that expected from the diagnosis. (c) There is a previous medical history of delayed recovery. (d) The patient is not a candidate where surgery or other treatments would clearly be warranted. (e) Inadequate employer support. (f) Loss of employment for greater than 4 weeks. The most discernable indication of at risk status is lost time from work of 4 to 6 weeks. (Mayer 2003) For general information see Chronic pain programs. **"Chronic pain programs, intensity** Recommend adjustment

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				according to patient variables, as indicated below. Research is ongoing as to what treatments are most necessary as part of interdisciplinary treatment for patients with subacute and chronic pain, and how intense such delivery of care should be. The more traditional models of interdisciplinary pain management often provide what has been referred to as tertiary care; a more intensive, and often, more palliative treatment for chronic pain. Research as to the intensity of treatment that is required for earlier intervention remains ongoing ("secondary intervention" see Chronic pain programs, early intervention). Several examples show the difference in results based on intensity of treatment that occur based, in part, on variables such as gender, age, prognosis, diagnosis, and duration of pain. A recent study showed that for men with low back pain that had been "sick-listed" for an average of 3 months, there was no difference between extensive multidisciplinary treatment and usual care in

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				terms of return to work. Significantly better results were found for men who received a "light treatment program" compared to usual care, and these results remained significant at 12, 18 and 24 months. (Skouen, 2002) On the other hand, an extensive program has been shown to be the most effective treatment modality for patients considered to be in categories of poor health, and poor prognosis who were "sick-listed" for the same period, although the effect tapers after one to two years. (Haldorsen, 2002) For general information see Chronic pain programs."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic pain programs***	Commenter indicates he objects to the sentence contained under the treatment guidelines ***Chronic pain programs***, p. 24, wherein it states: "Treatment is not suggested for longer than 2 weeks without evidence of demonstrated efficacy as documented by subjective and objective gains." Commenter states that the proposed criterion is objectionable because it allows carriers, insurance companies, and utilization review companies to use a method that wrongly delays and denies care. Commenter indicates that the language promoting two-week utilization review periods makes it difficult, sometimes impossible; to get timely renewals especially when a two-week reporting period and the end of authorized treatment arrive simultaneously. Commenter states that gaps in treatment occur when the treating physician is obliged by bureaucracy to wait for renewed authorization that	Robert L. Weinmann, M.D. President, Union of American Physicians and Dentists Independent Practice Association August 12, 2008	**Agree in part.** See response to comment submitted by William G. Brose, M.D., Health Education for Living with Pain, dated August 8, 2008, on the individual treatment guideline of Chronic pain programs, above.	See action taken in connection with comment submitted by William G. Brose, M.D., Health Education for Living with Pain, dated August 8, 2008, on the individual treatment guideline of ***Chronic pain programs***, above.

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	ends up delaying treatment and reducing its efficacy when it is finally approved. Commenter adds that insurance companies often cause untimely gaps in treatment which undermine treatment. Commenter states that an example is delaying the 2nd in a series of recommended epidural blocks. Commenter states that insurance companies may assert a need for "evidence of demonstrated efficacy" and then reject whatever "evidence of demonstrated efficacy" is offered.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic pain programs***	Commenter references sentence in treatment guideline stating that : "Treatment is not suggested for longer than 2 weeks without evidence of demonstrated efficacy as documented by subjective and objective gains." In reference to the quoted language, commenter states while he agrees with the underlined statement, he is concerned that in practice, carriers will only allow two week authorization periods yet make it impossible to communicate to obtain a timely extension. Commenter indicates that he appreciates that a pain program shouldn't keep injured workers who are not improving, but from a practical standpoint, he anticipates great problems obtaining continued authorization when the recommended two week reporting period and the end of authorized treatment coincide. Commenter adds that to illustrate, consider that following the guidance provided above, one would expect that every two weeks, a report would be filed that demonstrates efficacy of the treatment completed during the prior two-weeks. Commenter states that since only two weeks of treatment would likely be authorized, the report would be accompanied by a request for further authorization. Commenter states that at this point no further treatment would be administered while the treating physician waits for further authorization. Commenter indicates that the	Stephen J. Cattolica AdvoCal August 7, 2008 Oral Comment August 12, 2008	**Agree in part.** See response to comment submitted by William G. Brose, M.D., Health Education for Living with Pain, dated August 8, 2008, on the individual treatment guideline of Chronic pain programs, above.	See action taken in connection with comment submitted by William G. Brose, M.D., Health Education for Living with Pain, dated August 8, 2008, on the individual treatment guideline of ***Chronic pain programs***, above.

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	Division can appreciate the "start-stop" nature of this cycle and the detrimental effect upon the progress and well-being of the injured worker that would assuredly follow. Commenter states that injured workers experiencing chronic pain should not be held hostage to bureaucratic delays in the midst of participating in a documented chronic pain program. Commenter states that he believes that the current language could be retained in order to preserve the value of periodic reports and "evidence of demonstrated efficacy." Commenter states that, however, it should not be retained without additional language that addresses the potential for the coincident combination of the end of an authorization period, the submission of the recommended report and a request for further authorization. Commenter recommends that the Division add language within this section or within CCR Title 8, § 9792.24.2, to the effect that in the context of a chronic pain program, the treating physician be granted the longest practical authorization period possible, commensurate with the anticipated length of the entire chronic pain program. Commenter further states, that in addition, claims administrators should be instructed that under such a circumstance, any subsequent requests for authorization shall always be processed as an expedited request and not be unreasonably delayed or denied when the recommended reporting period and need to make such a request coincide in the midst of a previously documented program.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter believes that the provision in the Chronic Pain Medical Treatment Guidelines (Section 2, "Chronic Pain Programs") that states: Treatment is not suggested for longer than 2 weeks without evidence of	Sue Borg, President California Applicants' Attorneys	**Agree in part.** See response to comment submitted by William G. Brose, M.D., Health Education for Living with Pain, dated August 8,	See action taken in connection with comment submitted by William G. Brose, M.D., Health

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments ***Chronic pain programs***	demonstrated efficacy as documented by subjective and objective gains" will cause problems. Commenter states that although she understands this sentence from a medical standpoint, in reality it will simply cause delays and interruptions of treatment in virtually every case. Commenter states that the way this will work is that claim adjusters will authorize only the initial two weeks of treatment. Commenter states that she hopes that following the Supreme Court's decision in *Sandhagen* that approval of treatment requests will be more expeditious, but it is a simple fact that if a physician requests an extension of treatment near the end of the initial two week period (which is likely because the physician will have to be able to demonstrate the efficacy of the treatment) it is a certainty that authorization will not be communicated in time to prevent an interruption of treatment. Commenter states that given that any interruption in treatment can be devastating to workers experiencing chronic pain problems, she suggests that this section be amended to provide that authorization shall be provided for the recommended course of treatment, but that biweekly the physician shall provide evidence to the claim adjuster of demonstrated efficacy as documented by subjective and objective gains. Commenter states that at the very least, she recommends that an initial authorization of 2 weeks of treatment should include an automatic extension of 2 added weeks where the physician provides evidence to the claim adjuster prior to the expiration of the initial 2 week period of demonstrated efficacy as documented by subjective and objective gains.	Association Written & Oral August 12, 2008	2008, on the individual treatment guideline of Chronic pain programs, above.	Education for Living with Pain, dated August 8, 2008, on the individual treatment guideline of ***Chronic pain programs***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter adds that without standards for frequency, duration, intensity and appropriateness in the guidelines, it is not clear how to provide meaningful utilization review of a request for authorization for	Brenda Ramirez, Claims and Medical Director California Workers'	**Agree in part.** The Chronic Pain Medical Treatment Guidelines have been revised to address commenter's concerns on the	The individual treatment topic guideline for ***Chronic Pain Programs*** has been revised at paragraph 1, page

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Part 2. Pain Intervention and Treatments ***Chronic Pain Programs***	multi-dimensional treatments such as a chronic pain multispecialty program; both how to determine the medical necessity for the program itself, and for the individual treatment components and procedures within the program. Commenter states that if the guidelines do not allow meaningful utilization review, injured workers are not assured of the most effective treatment and are at risk of receiving inadequate or unnecessary treatment.	Compensation Institute August 12, 2008	standards for frequency, duration, intensity and appropriateness in the individual topic treatment guideline of chronic pain programs. In this regard, this guideline specifically provides criteria for appropriateness. Programs are structured to be time limited with a beginning and an end. Therefore, the treatment duration is defined. The appropriateness of the treatment is monitored during the program by progress reports. The intensity of the Chronic pain programs is reflected as the programs represent an integration of many disciplines and function as a whole, the components of which may vary depending on the program. These programs operate continuously with a defined daily schedule of rehabilitation activities for the patient, thus representing the frequency and duration required by the statute. For these reasons, **disagree** that the guidelines do not provide for meaningful utilization review. Nevertheless, ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "Chronic Pain Programs." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	32, as follows: **"Criteria for the general use of multidisciplinary pain management programs:** Outpatient pain rehabilitation programs may be considered medically necessary when all of the following criteria are met: "(1) An adequate and thorough evaluation has been made, including baseline functional testing so follow-up with the same test can note functional improvement; (2) Previous methods of treating the chronic pain have been unsuccessful and there is an absence of other options likely to result in significant clinical improvement; (3) The patient has a significant loss of ability to function independently resulting from the chronic pain; (4) The patient is not a candidate where surgery or other treatments would clearly be warranted (if a goal of treatment is to prevent or avoid controversial or optional surgery, a trial of 10 visits may be implemented to assess whether surgery may be avoided); (5) The patient

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				exhibits motivation to change, and is willing to forgo secondary gains, including disability payments to effect this change; & (6) Negative predictors of success above have been addressed."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic Pain Programs***	Commenter references the ***Chronic Pain Programs*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline under the types of treatment by adding one category under letter (g): "Types of treatment: Components suggested for interdisciplinary care include the following services delivered in an integrated fashion: (a) physical treatment; (b) medical care and supervision; (c) psychological and behavioral care; (d) psychosocial care; (e) vocational rehabilitation and training; and (f) education <u>(g) clinical urine drug testing UPLCMS-MS-U – ultraperformance liquid chromatography – mass – spec – mass spec."</u>	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic Pain Programs***	Commenter references the ***Chronic Pain Programs*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at pages 23-24, last paragraph, as follows: "The following variables have been found to be negative predictors of efficacy of treatment with the programs as well as negative predictors of completion of the programs: (1) a negative relationship with the employer/supervisor; (2) poor work adjustment and	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	satisfaction; (3) a negative outlook about future employment; (4) high levels of psychosocial distress (higher pretreatment levels of depression, pain and disability); (5) involvement in financial disability disputes; (6) greater rates of smoking cannabis and use of alcohol; (7) duration of pre-referral disability time; (8) prevalence of opioid use, abuse, misuse; and (9) pre-treatment levels of pain. Failure or refusal of clinical urine drug testing. Patient agenda (personal)."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic Pain Programs***	Commenter references the ***Chronic Pain Programs*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, at page 24, last paragraph, as follows: "They may be appropriate for patients who: (1) don't have the minimal functional capacity to participate effectively in an outpatient program; (2) have medical conditions that require more intensive oversight; (3) are receiving large amounts of medications necessitating medication weaning or detoxification clinical urine drug testing(UPLC/MS/MS); or (4) have complex medical or psychological diagnosis that benefit from more intensive observation and/or additional consultation during the rehabilitation process. (Keel, 1998) (Kool, 2005) (Buchner, 2006) (Kool, 2007) As with outpatient pain rehabilitation programs, the most effective programs combine intensive, daily biopsychosocial rehabilitation with a functional restoration approach. Patient genuine desire for beneficial therapeutic outcome to increase functionally, ADL's [activity of daily living] and return to work."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	None.
9792.24.2(a) Chronic Pain	Commenter proposes that DWC change the language from "physical therapy" to "occupational therapy and	Shawn Phipps, President	**Disagree.** In adapting ODG's new version dated October 23, 2008,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic pain programs***	physical medicine" in the ***Chronic pain programs*** of the Chronic Pain Medical Treatment Guidelines as occupational therapists play a critical role in the treatment of chronic pain.	Occupational Therapy Association of California August 8, 2008	DWC has modified the language of the revised version to conform to the concept of "physical medicine," which encompases both occupational therapy and physical therapy. Thus, the adapted guidelines were changed as follows: Where ODG references "Physical therapy" without mention of "Occupational therapy," DWC modified "Physical therapy" to "Physical medicine" to conform to DWC's decision to list Physical therapy and Occupational therapy under the heading "Physical medicine." Commenter's suggested changes do not conform to the formatting of the guidelines.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Chronic pain programs***	Commenter proposes that DWC change the language from "physical therapy" to "occupational therapy and physical medicine" in the ***Chronic pain programs*** of the Chronic Pain Medical Treatment Guidelines as occupational therapists play a critical role in the treatment of chronic pain.	Charles Willmarth, Director, State Affairs and Reimbursement & Regulatory Policy The American Occupational Therapy Association, Inc. August 11, 2008	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, August 8, 2008, on section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Chronic pain programs, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Cod liver oil [DWC]***	Commenter agrees with guideline.	Theodore Blatt, M.D. Medical Director, Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndrome (CRPS)***	Commenter references the **Complex Regional Pain Syndrome (CRPS)** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline, in pertinent part, as follows: 2. Stimulus-independent pain: The use of antidepressants, anticonvulsants, and opioids has been primarily extrapolated based on use for other neuropathic pain disorders. (See Antidepressants for neuropathic pain; Anticonvulsants for chronic pain; & Opioids for neuropathic pain.) Mexiletine ~~(oral lidocaine)~~, lidocaine patches and capsaicin are used but efficacy is not convincing. For central inhibition opiates, gabapentin, TCAs, GABA-enhancing drugs, and clonidine may be useful. 3. Stimulus-evoked pain: treatment is aimed at central sensitization. With NMDA receptor antagonists EX:(ketamine and amantadine) convincing controlled trials are lacking, and these drugs are ~~known~~ recognized for their side effects.	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** that clarification is necessary in this regard. ODG has modified the individual treatment guideline for Complex Regional Pain Syndrome (CRPS) at p. 38, item number 2, under the subtitle CRPS, medications for clarifications purposes to delete the language "(oral lidocaine)" after the word "Mexiletine." **Disagree** with the remaining editing comments. The recommended changes are general editing comments which are inconsistent with ODG's style and do not address the substance of the regulations.	The individual treatment guideline for ***Complex Regional Pain Syndrome (CRPS)*** at p. 38, item number 2, under the subtitle CRPS, medications is modified as follows: "2. Stimulus-independent pain: The use of antidepressants, anticonvulsants, and opioids has been primarily extrapolated based on use for other neuropathic pain disorders. (See **Antidepressants for** ~~neuropathic~~ **chronic pain**; **Anticonvulsants for chronic pain**; & **Opioids for neuropathic pain**.) Mexiletine ~~(oral lidocaine)~~, lidocaine patches and capsaicin are used but efficacy is not convincing. For central inhibition opiates, gabapentin, TCAs, GABA-enhancing drugs, and clonidine may be useful."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndromes***	Commenter states that the ***Chronic Regional Pain Syndromes (CRPS)*** [sic] treatment guideline in the DWC Chronic Pain Medical Treatment Guidelines is 4 pages long and it is an extremely superficial discussion of a complicated matter. Commenter adds that the ***Chronic Regional Pain Syndromes (CRPS)*** [sic] treatment guideline in the ACOEM Chronic Pain Update is an entire multi-page section and contains multiple recommendations.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** With regard to commenter's opinion that the DWC Chronic Pain Medical Treatment Guidelines individual treatment topic guideline on Complex Regional Pain Syndromes (CRPS) is superficial, commenter does not offer a specific example. Thus, his comment is non-responsive and	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
(CRPS)			does not address the substance of the proposed regulations.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndromes (CRPS)*** ***CPRS, Medications***	Commenter makes references to ***CPRS, Medications*** treatment recommendation in the Chronic Pain Medical Treatment Guidelines. Commenter states that the section on CRPS Regional inflammatory reaction, groups DMSO creams, IV administration and oral corticosteroids contains the statement that there is "little likelihood for harm [sic]." Commenter argues that this statement is contrary to accepted clinical training – any IV administration needs to be considered at higher risk than topical administration. (DWC Chronic Pain Medical Treatment Guidelines, Page 25, par 6.)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree.** DWC **agrees** with commenter's statement. ODG has corrected its guideline to strike statement regarding the relative harm of DMSO creams, IV administration and oral corticosteroids medication treatments in connection with CRPS.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Complex Regional Pain Syndromes (CRPS), CPRS, Medications,*** has been amended at page 38, paragraph no. 2, as follows: "1. Regional inflammatory reaction: Commonly used drugs are NSAIDS, corticosteroids and free-radical scavengers. There is some evidence of efficacy ~~and little likelihood for harm~~ for topical DMSO cream, IV bisphosphonates and limited courses of oral corticosteroids. Corticosteroids are most effective when positive response is obtained with sympathetic blocks. NSAIDs are recommended but no trials have shown effectiveness in CRPS-I, and they are recommended primarily in early or very late stages. (Stanton-Hicks, 2004) (Sharma, 2006)"
9792.24.2(a) Chronic Pain Medical Treatment	Commenter addresses the ***Complex Regional Pain Syndromes (CRPS), CRPS, Medications, Bisphosphonates***. Commenter states that the section	ACOEM Barry Eisenberg, Executive Director	**Agree.** ODG has performed an evidence-based review on the topic as of August 13, 2008, and the	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndromes (CRPS)*** ***CPRS, Medications, Bisphosphonates***	ends with bisphosphonates which appear to produce the largest magnitude reductions in pain ratings for CRPS patients and most of the relevant trials were not cited (also note that this was not mentioned for pain management on page 28). Commenter states that the guidelines' stated assumption that the effects of bisphosphonates are due to effects on bone resorption demonstrates that the literature on this subject was not comprehensively reviewed, as the effects are thought to potentially involve avenues other than inhibition of bone resorption. (Manicourt 04, Varenna 00, Adami 97, Robinson 04) (DWC Chronic Pain Medical Treatment Guidelines, page 25, par 6.)	August 7, 2008	subject has been updated. An individual treatment guideline topic Bisphosphonates has been created. The guideline as adapted has been incorporated into the DWC guidelines.	Intervention and Treatments ***Complex Regional Pain Syndromes (CRPS, CPRS, Medications,*** has been amended by adding a new individual treatment guideline topic entitled, ***Bisphosphonates,*** at page 25 as follows: **"Bisphosphonates** Recommend treatment of bone resorption with bisphosphonate-type compounds as an option for patients with CRPS Type I. Not recommended for other chronic pain conditions. Signifcant improvement has been found in limited studies of intravenous clodronate and intravenous alendronate. Alendronate (Fosamax®) given in oral doses of 40 mg a day (over an 8 week period) produced improvements in pain, pressure tolerance and joint mob[i]lity. The effects may potentially involve avenues other than inhibition of bone resorption. (Manicourt, 2004) See also CRPS, medications. Bisphosphonates are a class of drugs that inhibit osteoclast action and the

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				resorption of bone. Alendronate (Fosamax®) is in this class."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndromes (CRPS)*** ***CRPS, treatment, Outcome measures***	Commenter references the text under the heading of Outcome measures for all treatments of CRPS. (DWC Chronic Pain Medical Treatment Guideline, page 29.) Commenter states that three of the outcomes measures listed (McGill Pain Questionnaire-Short Form, the Pain Disability Index and Treatment Outcomes in Pain Survey) do not meet the APA standards for standardized test in clinical use (American Education Research Association 1999).	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree.** ODG conducted its own evidence-based review. ODG determined based on its own evidence-based review that the commenter is correct that the last three outcome measures listed (McGill Pain Questionnaire-Short Form, the Pain Disability Index and Treatment Outcomes in Pain Survey) may not meet the APA standards for standardized test in clinical use (American Education Research Association 1999). ODG amended its guidelines to add a modifier in reference to this outcome measures stating that they "may not meet APA standards." DWC **agrees** with ODG's correction to its guideline and has adopted its correction into its adapted version.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Complex Regional Pain Syndromes (CRPS), CRPS, treatment,*** has been amended, at page 42, last paragraph, as follows: "Outcome measures for all treatments of CRPS: Objective measures such as the Beck Depression Inventory, the State Trait Anxiety Inventory, McGill Pain Questionnaire-Short Form, the Pain Disability Index, ~~the Beck Depression Inventory,~~ & the Treatment Outcomes in Pain Survey (the last three may not meet the APA standards for standardized test in clinical use)~~, and the State Trait Anxiety Inventory~~. See Psychological evaluations. See also CRPS, diagnostic criteria; CRPS, medications; CRPS, prevention; CRPS, sympathetic blocks; & Sympathetically maintained pain (SMP). See also Spinal cord stimulators (SCS)"

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndromes (CRPS)*** ***CPRS, Medications, Calcitonin***	Commenter states that **Calcitonin** is suggested to have "Mixed results." Commenter indicates that however, there are 3 quality RCTs, and both of the higher rated studies show benefits (Bickerstaff 91, Gobelet 92) with one lower quality exception (Sahin 06). (Commenter references DWC Page 24, par 2, correct reference is page 26, par 2.)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree.** ODG has performed an evidence-based review on the topic as of August 13, 2008, and the subject has been updated. An individual treatment guideline topic Calcitonin has been created. The guideline as adapted has been incorporated into the DWC guidelines.	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndromes (CRPS, CPRS, Medications,*** has been amended by adding a new individual treatment guideline topic entitled, ***Calcitonin,*** at page 28 as follows: **"Calcitonin** Recommended as a treatment option for patients with CRPS Type I with a contraindication for treatment of bone resorption with a bisphosphonate. Not recommended for other chronic pain conditions. Signifcant improvement has been found in limited studies of intravenous clodronate and intravenous alendronate. Alendronate (Fosamax®) given in oral doses of 40 mg a day (over an 8 week period) produced improvements in pain, pressure tolerance and joint mob[i]lity. (Manicourt, 2004) Mixed results have been found with intranasal calcitonin (Miacalcin®). (Sahin, 2005) (Appelboom, 2002) (Rowbathan, 2006)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				(Sharma, 2006) See also CRPS, medications. Calcitonin is a hormone known to participate in calcium and phosphorus metabolism."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Complex Regional Pain Syndrome (CRPS)*** ***CRPS, medications***	Commenter highlights the language, "Recommended only as indicated below." Commenter believes this section and the naming of specific drugs and types of drugs should be edited for clarification to assist the user of these protocols.	Theodore Blatt, M.D. Medical Director Anthem Blue Cross July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***CRPS, spinal cord stimulators (SCS)***	Commenter references the ***CRPS, spinal cord stimulators (SCS)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended as indicated below. Spinal cord stimulators (SCS) should be offered only after careful professional counseling and significant patient identification and should be used in conjunction with comprehensive multidisciplinary medical management. CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. SCS use has been associated with pain reduction in studies of patients with with CRPS. Moreover, there is evidence to demonstrate that SCS is a cost-effective treatment for CRPS-I over the long term. (Taylor, 2006) (Stanton-Hicks, 2006) (Mailis-Gagnon-Cochrane, 2004) (Kemler, 2000) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language. Nevertheless, through ODG's internal evidence evaluation review process, ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "CRPS, spinal cord stimulators (SCS)". DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	The Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***CRPS, spinal cord stimulators (SCS)*** has been amended as follows: **"CRPS, spinal cord stimulators (SCS)** "Recommended as indicated below. Spinal cord stimulators (SCS) should be offered only after careful counseling and patient identification and should be used in conjunction with comprehensive multidisciplinary medical management. SCS use has been associated with pain

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	with physical therapy. (Harke, 2005) See Spinal cord stimulators (SCS). Significant opioid decrements appear not to be reported."			reduction in studies of patients with CRPS. (Kemler, 2000) (Kemler, 2004) (Kemler, 2008) CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. (Taylor, 2006) ~~SCS use has been associated with pain reduction in studies of patients with with CRPS.~~ Moreover, there is evidence to demonstrate that SCS is a cost-effective treatment for CRPS-I over the long term. ~~(Taylor, 2006)~~ (Stanton-Hicks, 2006) (Mailis-Gagnon-Cochrane, 2004) (Kemler, 2000) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined with physical therapy. (Harke, 2005) See Spinal cord stimulators (SCS)."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***CRPS, spinal cord stimulators (SCS)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Spinal cord stimulators (SCS) should be offered only after careful counseling and patient identification and should be used in conjunction with comprehensive multidisciplinary medical management."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain	Commenter references the ***CRPS, sympathetic and epidural blocks*** treatment guideline contained in Part	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve	Section 9792.24.2(a), Chronic Pain Medical

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***CRPS, sympathetic and epidural blocks***	2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "See also Sympathetically maintained pain (SMP). Significant decreases in opioid use by patients remains to be identified."		the guideline language. Nevertheless, thorough ODG's internal evidence evaluation review process, ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "CRPS, sympathetic and epidural blocks." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***CRPS, sympathetic and epidural blocks,*** has been modified as follows: **"CRPS, sympathetic and epidural blocks** "Recommended only as indicated below, for a limited role, ~~when used for symptom relief and to demonstrate~~ primarily for diagnosis of sympathetically ~~maintained~~ mediated pain ~~(SMP)~~ and as an adjunct to facilitate physical therapy. ~~(Stanton-Hicks, 2004)~~ Detailed information about stellate ganglion blocks, thoracic sympathetic blocks, and lumbar sympathetic blocks is found in Regional sympathetic blocks. Recommendations for the use of sympathetic blocks are listed below. They are recommended for a limited role, primarily for diagnosis of sympathetically mediated pain and as an adjunct to facilitate physical therapy. It should be noted that sympathetic blocks are not specific for CRPS. See Sympathetically maintained

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				pain (SMP). Repeated blocks are only recommended if continued improvement is observed. ~~A s~~Systematic reviews revealed a paucity of published evidence supporting the use of local anesthetic sympathetic blocks for the treatment of CRPS and usefulness remains controversial. Less than 1/3 of patients with CRPS are likely to respond to sympathetic blockade. No controlled trials have shown any significant benefit from sympathetic blockade. (Varrassi, 2006) (Cepeda, 2005) (Hartrick, 2004) (Grabow, 2005) (Cepeda, 2002) (Forouzanfar, 2002) (Sharma, 2006) ~~Regional sympathetic blocks are used for (1) Upper extremity: Stellate ganglion blocks or laparoscopic blocks; or (2) Lower extremity: Lumbar sympathetic block. Signs of a successful block: Temperature rise to 35°; Sympathetic skin response using modified ECG; Cold pressor test; Laser Doppler flowmetry. This type of evaluation is important, especially if the block is unsuccessful in eliminating pain in order to determine if~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~a complete block was performed. A sensory examination should also be completed in patients with pain relief. Local anesthetic can also result in somatic block that can affect pain. Pain relief may also be due to systemic uptake of local anesthetic or a placebo effect. (Grabow, 2005) Evaluating and treating results should include: (1) Complete elimination of pain: consider prolonged neurolytic block; consider the use of a α1 adrenoceptor blocker such as terazosin; & (2) Current suggested guidelines suggest that a maximum sustained benefit is obtained after 3 to 6 blocks when used in addition to PT. (Washington, 2002) (Stanton-Hicks, 2006) They also state that even if the original site is unresponsive, future exacerbations of CRPS at the same site or distant site may respond to 1 to 3 blocks. (Washington, 2002)~~ *Predictors of poor response:* Long duration of symptoms prior to intervention; Elevated anxiety levels; Poor coping skills; Litigation. (Hartrick, 2004) (Nelson, 2006)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Alternatives to regional sympathetic blocks: may be necessary when there is evidence of coagulopathy, systemic infection, and/or post-surgical changes. These include peripheral nerve and plexus blocks and epidural administration of local anesthetics. *Mixed conduction blocks (central neural blocks*): suggested when analgesia is insufficient by pharmacologic means to support physical therapy: (1) Implanted catheters at the brachial or lumbosacral plexus: allows for 1 to 2 weeks of therapy. Side effects include technical failure and infection; & (2) Epidural tunneled catheters: allows for long-term therapy: Side effects: same as above. *Clonidine* has also been effective epidurally. (Stanton-Hicks, 2006) *Baclofen* has been demonstrated to be effective intrathecally to reduce dystonia. (van Hilten, 2000) *IV regional sympathetic blocks*: controversial due to varying success. Guanethadine was used, but is no longer available in the US. Bretylium and reserpine

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				require daily blocks, and have potential side effects of transient syncope with apnea, orthostatic hypotension, pain with administration, nausea and vomiting. Bretylium provided ~~a~~ more than 30% ~~improvement in~~ pain relief for a mean of 20 days compared to placebo. (Hord, 1992) Due to modest benefits and the invasiveness of the therapies, epidural clonidine injection and intravenous regional sympathetic block with bretylium should be offered only after careful counseling, and they should be followed by intensive physical therapy. Intravenous regional sympathetic block (Bier's block, 25 sessions) with guanethidine and lidocaine resulted in excellent pain relief and full restoration of both function and range of movement of the affected extremity in patients suffering from CRPS-I of the hand. (Paraskevas, 2005) Local or systemic parecoxib combined with lidocaine/clonidine IV regional analgesia is an effective treatment for

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				CRPS-I in a dominant upper limb. (Frade, 2005) See also **Sympathetically maintained pain (SMP)**; & **Regional sympathetic blocks**. **Recommendations (based on consensus guidelines) for use of sympathetic blocks:** (1) In the initial diagnostic phase if less than 50% improvement is noted for the duration of the local anesthetic, no further blocks are recommended. (2) In the initial therapeutic phase, maximum sustained relief is generally obtained after 3 to 6 blocks. These blocks are generally given in fairly quick succession in the first two weeks of treatment with tapering to once a week. Continuing treatment longer than 2 to 3 weeks is unusual. (3) In the therapeutic phase repeat blocks should only be undertaken if there is evidence of increased range of motion, pain reduction and increased tolerance of activity and touch in physical therapy/occupational therapy. (4) There should be evidence that physical or occupational therapy is incorporated with the duration of symptom relief

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				of the block during the therapeutic phase. (5) In acute exacerbations, 1 to 3 blocks may be required for treatment. (5) A formal test of the block should be documented (preferably using skin temperature). (6) Documentation of motor and/or sensory block should occur. This is particularly important in the diagnostic phase to avoid overestimation of the sympathetic component of pain. (Burton, 2006) (Stanton-Hicks, 2004) (Stanton-Hicks, 2006) (International Research Foundation for RSD/CRPS, 2003) (Colorado, 2006) (Washington, 2002) (Rho, 2002)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***CRPS, sympathectomy***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Not recommended." Additionally, commenter questions the following statement: "Local anesthetic Stellate Ganglion Block or Lumbar Sympathetic Block consistently gives 90 to 100 percent relief each time a technically good block is performed (with measured rise in temperature). The procedure may be considered for individuals who	Theodore Blatt, M.D. Medical Director Anthem Blue Cross July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	have limited duration of relief from blocks." Commenter questions whether this statement is intended to mean that patients who have had a good but temporary response to the sympathetic blocks ARE candidates for their sympathectomy. Commenter states that clarification is needed.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***CRPS, sympathetic and epidural blocks***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends eliminating all but the following language: "Recommended when used for symptom relief and to demonstrate sympathetically maintained pain (SMP)." A systematic review revealed a paucity of published evidence supporting the use of local anesthetic sympathetic blocks for the treatment of CRPS. (Cepeda, 2005) Regional sympathetic blocks are used for (1) Upper extremity: Stellate ganglion blocks or laparoscopic blocks; or (2) Lower extremity: Lumbar sympathetic block. Signs of a successful block: Temperature rise to 35°; Sympathetic skin response using modified ECG; Cold pressor test; Laser Doppler flowmetry. This type of evaluation is important, especially if the block is unsuccessful in eliminating pain in order to determine if a complete block was performed. A sensory examination should also be completed in patients with pain relief. Local anesthetic can also result in somatic block that can affect pain. Pain relief may also be due to systemic uptake of local anesthetic or a placebo effect. (Grabow, 2005) Evaluating and treating results should include: (1) Complete elimination of pain: consider prolonged neurolytic block; consider the use of a α1 adrenoceptor blocker such as terazosin; & (2) Current suggested guidelines suggest that maximum sustained benefit is obtained after 3 to 6 blocks when	Theodore Blatt, M.D. Medical Director Anthem Blue Cross July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	used in addition to PT. Alternatives to regional sympathetic blocks may be necessary when there is evidence of coagulopathy, systemic infection, and/or post-surgical changes. These include peripheral nerve and plexus blocks and epidural administration of local anesthetics. Mixed conduction blocks (central neural blocks) are suggested when analgesia is insufficient by pharmacologic means to support physical therapy: (1) Implanted catheters at the brachial or lumbosacral plexus: allows for 1 to 2 weeks of therapy. Epidural tunneled catheters: allows for long-term therapy With regard to the statement number two above which states: "(2) Current suggested guidelines suggest that maximum sustained benefit is obtained after 3 to 6 blocks when used in addition to PT," commenter questions whether this statement mean that a maximum of 6 blocks be given. Commenter states that his organization has traditionally assessed continued blocks by functional improvement and questions whether that is contrary to this guideline. Commenter also highlights a sentence in the guideline which states, "IV regional sympathetic blocks are controversial due to varying success." Commenter indicates that IV regional blocks are not uncommonly requested and he believes the user of this document would benefit from a definitive statement regarding the efficacy.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and	Commenter references the text under the heading "CRPS, treatment." Commenter states that on page 29, the document lists several tests, the McGill Pain Questionnaire-Short Form, the Pain Disability Index, the Beck Depression Inventory, Treatment Outcomes in Pain Survey, and the State Trait Anxiety Inventory.	Daniel Bruns, PsyD Licensed Psychologist July 18, 2008	**Agree in part.** ODG conducted its own evidence-based review. ODG determined based on its own evidence-based review that the commenter is correct in part in his comment regarding the outcome	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Complex Regional Pain Syndromes***

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments ***Complex Regional Pain Syndromes (CRPS)*** ***CRPS, treatment***	Commenter states that although several references are listed, the Pain Disability Index, and the Treatment Outcomes in Pain Survey are not listed elsewhere. Commenter indicates that more importantly, only two of the measures listed here (BDI, STAI) meet the standards of the American Psychological Association as an acceptable standardized test to be used for clinical purposes (See American Educational Research Association, American Psychological Association, et al. (1999). Standards for educational and psychological testing. Washington, DC, American Educational Research Association.) Commenter states that, consequently, some of the outcome measures listed here are of questionable value for clinical use, and the reader is offered no information or references with regard to the uses, strengths or weaknesses of the (Pain Disability Index, Treatment Outcomes in Pain Survey).		measures for all treatments of CRPS. ODG amended its guidelines to reflect the outcome measures that meet the standards of the American Psychological Association (APA) as an acceptable standardized test to be used for clinical purposes. DWC **agrees** with ODG's correction to its guideline and has adopted its correction into its adapted version.	***(CRPS), CRPS, treatment*** has been amended as follows: **"CRPS, treatment** "Recommended hierarchy of options as indicated below. The goal is to improve function. Multiple pathophysiological mechanisms are responsible including neuropathic (sympathetic and independently-maintained pain), and immunologic (regional inflammation and altered human leukocyte antigens). Both peripheral sensitization and central sensitization have been proposed. (Ribbers, 2003) (Stanton-Hicks, 2006) There are no evidence-based treatment guidelines but several groups have begun to organize treatment algorithms. "Recommendations: 1. Rehabilitation: (a) *Early stages*: Build a therapeutic alliance. Analgesia, encouragement and education are key. Physical modalities include desensitization, isometric exercises, resisted range of motion, and stress loading. If

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				not applied appropriately, PT can actually be detrimental. (b) *Next steps*: Increase flexibility with introduction of gentle active ROM and stretching (to treat accompanying myofascial pain syndrome). Other modalities may include muscle relaxants, trigger point injections and electrical stimulation (based on anecdotal evidence). Edema control may also be required (elevation, retrograde sympathetic blocks, diuretics and adrenoceptor blockers when sympathetically maintained pain-SMP is present). (c) *Continued steps*: Continue active ROM; stress loading; scrubbing techniques; isotonic strengthening; general aerobic conditioning; and postural normalization. (d) *Final steps*: Normalization of use; assessment of ergonomics, posture and modifications at home and work. In some cases increased requirements of analgesic medications, psychotherapy, invasive anesthetic techniques and SCS may be required. See CRPS, spinal cord stimulators.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				2. Psychological treatment: Focused on improved quality of life, development of pain coping skills, cognitive-behavioral therapy, and improving facilitation of other modalities. (a) *Early stages*: education. (b) *Next steps*: clinical psychological assessment (after 6 to 8 weeks): identification of stressors; identification of comorbid Axis I psychiatric disorders (depression, anxiety, panic and post-traumatic stress). 3. Pain management: (a) *Pharmacological*: antidepressants (particularly amitriptyline); anticonvulsants (particularly gabapentin); steroids; NSAIDS; opioids; calcitonin; bisphosphonates; α1 adrenoceptor antagonists (terazosin or phenoxybenzamine). The latter class of drugs has been helpful in SMP. Clonidine has been given transdermally and epidurally. (See CRPS, medications.) Bisphosphonates have some literature support in the presence of osteopenia. (Rho, 2002) (b) *Minimally invasive*: depends on degree of SMP, stage of

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				rehabilitation (passive or active movement), and response to blocks. (See CRPS, sympathetic blocks.) Responders to sympathetic blocks (3 to 6 blocks with concomitant PT) may be all that is required. For non-responders somatic block or epidural infusion may be required to optimize analgesia for PT. (c) *More invasive*: After failure of progression or partial relief, consider tunneled epidural catheters for prolonged sympathetic or somatic blocks or neurostimulation with SCS in CRPS-I and II. See CRPS, spinal cord stimulators. Also consider peripheral nerve stimulation in CRPS-II and intrathecal drug delivery in patients with dystonia, failed neurostimulation, long-standing disease, multi-limb involvement and requirement of palliative care. (d) *Surgical*: Sympathectomy is not generally recommended, but has been considered in patients that respond to sympathetic blocks. Pre-procedure the patient should have outcomes assessed with radiofrequency and neurolytic procedures. (See

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				CRPS, sympathectomy.) Motor Cortex Stimulation has been considered. Outcome measures for all treatments of CRPS: Objective measures such as the Beck Depression Inventory, the State Trait Anxiety Inventory, McGill Pain Questionnaire-Short Form, the Pain Disability Index, ~~the Beck Depression Inventory,~~ & the Treatment Outcomes in Pain Survey (the last three may not meet the APA standards for standardized test in clinical use)~~, and the State Trait Anxiety Inventory~~. See Psychological evaluations. See also CRPS, diagnostic criteria; CRPS, medications; CRPS, prevention; CRPS, sympathetic blocks; & Sympathetically maintained pain (SMP). See also Spinal cord stimulators (SCS)."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***CRPS, treatment***	Commenter does not see the need for this section as this topic has been adequately covered in previous sections.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***CRPS, treatment***	Commenter references the ***CRPS, treatment*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "1. Rehabilitation: (a) *Early stages*: Build a therapeutic alliance. Analgesia, encouragement and education are key. Physical modalities include desensitization, isometric exercises, resisted range of motion, and stress loading. If not applied appropriately, PT can actually be detrimental. (b) *Next steps*: Increase flexibility with introduction of gentle active ROM and stretching (to treat accompanying myofascial pain syndrome). Other modalities may include muscle relaxants, trigger point injections and electrical stimulation (based on anecdotal evidence). Edema control (avoid NSAIDs, pregabalin) may also be required (elevation, retrograde sympathetic blocks, diuretics and adrenoceptor blockers when sympathetically maintained pain-SMP is present). (c) *Continued steps*: Continue active ROM; stress loading; scrubbing techniques; isotonic strengthening; general aerobic conditioning; and postural normalization. (d) *Final steps*: Normalization of use; assessment of ergonomics, posture and modifications at home and work. In some cases increased requirements of selected analgesic medications, psychotherapy, invasive anesthetic techniques and SCS may be required. See CRPS, spinal cord stimulators." Commenter further references the ***CRPS, treatment*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows:	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language. Nevertheless, through ODG's internal evidence evaluation review process, ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "CRPS, treatment." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***CRPS, treatment***, has been amended as follows: **"CRPS, treatment** "Recommended hierarchy of options as indicated below. The goal is to improve function. Multiple pathophysiological mechanisms are responsible including neuropathic (sympathetic and independently-maintained pain), and immunologic (regional inflammation and altered human leukocyte antigens). Both peripheral sensitization and central sensitization have been proposed. (Ribbers, 2003) (Stanton-Hicks, 2006) There are no evidence-based treatment guidelines but several groups have begun to organize treatment algorithms. Recommendations: 1. Rehabilitation: (a) *Early stages*: Build a therapeutic alliance. Analgesia, encouragement and education are key. Physical

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	"3. Pain management: (a) *Pharmacological*: antidepressants (~~particularly~~ ex: amitriptyline or SNRI's [serotonin-norepinephrine reuptake inhibitor]); anticonvulsants (~~particularly~~ ex: gabapentin); steroids; NSAIDS; opioids; calcitonin; α1 adrenoceptor antagonists (terazosin or phenoxybenzamine). The latter class of drugs has been helpful in SMP. Clonidine has been given transdermally and epidurally. (See CRPS, medications.) (b) *Minimally invasive*: depends on degree of SMP, stage of rehabilitation (passive or active movement), and response to blocks (1-6 under c-arm). (See CRPS, sympathetic blocks.) Responders to sympathetic blocks (3 to 6 blocks with concomitant PT) may be all that is required. For non-responders somatic block or epidural infusion may be required to optimize analgesia for PT. (c) *More invasive*: After failure of progression or partial relief, consider tunneled epidural catheters for prolonged sympathetic or somatic blocks or neurostimulation with SCS in CRPS-I and II. See CRPS, spinal cord stimulators. Also consider peripheral nerve stimulation in CRPS-II and intrathecal drug delivery in patients with dystonia, failed neurostimulation, long-standing disease, multi-limb involvement and requirement of palliative care. (d) *Surgical*: Sympathectomy is not generally recommended, but has been considered in patients that respond to sympathetic blocks. Pre-procedure the patient should have outcomes assessed with radiofrequency and neurolytic procedures. (See CRPS, sympathectomy.) Motor Cortex Stimulation has been considered. Outcome measures for all treatments of CRPS: Objective measures such as the McGill Pain Questionnaire-Short Form, the Pain Disability Index, the Beck Depression Inventory, Treatment Outcomes in Pain Survey, and the State Trait Anxiety Inventory. See Psychological evaluations. See also CRPS,			modalities include desensitization, isometric exercises, resisted range of motion, and stress loading. If not applied appropriately, PT can actually be detrimental. (b) *Next steps*: Increase flexibility with introduction of gentle active ROM and stretching (to treat accompanying myofascial pain syndrome). Other modalities may include muscle relaxants, trigger point injections and electrical stimulation (based on anecdotal evidence). Edema control may also be required (elevation, retrograde sympathetic blocks, diuretics and adrenoceptor blockers when sympathetically maintained pain-SMP is present). (c) *Continued steps*: Continue active ROM; stress loading; scrubbing techniques; isotonic strengthening; general aerobic conditioning; and postural normalization. (d) *Final steps*: Normalization of use; assessment of ergonomics, posture and modifications at home and work. In some cases increased requirements of analgesic medications, psychotherapy, invasive

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	diagnostic criteria; CRPS, medications; CRPS, prevention; CRPS, sympathetic blocks; & Sympathetically maintained pain (SMP). See also Spinal cord stimulators (SCS). Clinical urine drug testing UPLC [Ultra Performance Liquid Chromatography]-ms/ms."			anesthetic techniques and SCS may be required. See CRPS, spinal cord stimulators. 2. Psychological treatment: Focused on improved quality of life, development of pain coping skills, cognitive-behavioral therapy, and improving facilitation of other modalities. (a) *Early stages*: education. (b) *Next steps*: clinical psychological assessment (after 6 to 8 weeks): identification of stressors; identification of comorbid Axis I psychiatric disorders (depression, anxiety, panic and post-traumatic stress). 3. Pain management: (a) *Pharmacological*: antidepressants (particularly amitriptyline); anticonvulsants (particularly gabapentin); steroids; NSAIDS; opioids; calcitonin; bisphosphonates; α1 adrenoceptor antagonists (terazosin or phenoxybenzamine). The latter class of drugs has been helpful in SMP. Clonidine has been given transdermally and epidurally. (See CRPS, medications.) Bisphosphonates have some literature support in the

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				presence of osteopenia. (Rho, 2002) (b) *Minimally invasive*: depends on degree of SMP, stage of rehabilitation (passive or active movement), and response to blocks. (See CRPS, sympathetic blocks.) Responders to sympathetic blocks (3 to 6 blocks with concomitant PT) may be all that is required. For non-responders somatic block or epidural infusion may be required to optimize analgesia for PT. (c) *More invasive*: After failure of progression or partial relief, consider tunneled epidural catheters for prolonged sympathetic or somatic blocks or neurostimulation with SCS in CRPS-I and II. See CRPS, spinal cord stimulators. Also consider peripheral nerve stimulation in CRPS-II and intrathecal drug delivery in patients with dystonia, failed neurostimulation, long-standing disease, multi-limb involvement and requirement of palliative care. (d) *Surgical*: Sympathectomy is not generally recommended, but has been considered in patients that respond to sympathetic blocks. Pre-

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				procedure the patient should have outcomes assessed with radiofrequency and neurolytic procedures. (See CRPS, sympathectomy.) Motor Cortex Stimulation has been considered. Outcome measures for all treatments of CRPS: Objective measures such as the Beck Depression Inventory, the State Trait Anxiety Inventory, McGill Pain Questionnaire-Short Form, the Pain Disability Index, ~~the Beck Depression Inventory,~~ & the Treatment Outcomes in Pain Survey (the last three may not meet the APA standards for standardized test in clinical use)~~, and the State Trait Anxiety Inventory~~. See Psychological evaluations. See also CRPS, diagnostic criteria; CRPS, medications; CRPS, prevention; CRPS, sympathetic blocks; & Sympathetically maintained pain (SMP). See also Spinal cord stimulators (SCS)."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter agrees with this guideline.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree**.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Curcumim (turmeric) [DWC]				
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Cyclobenzaprine (Flexeril®)***	Commenter references the ***Cyclobenzaprine (Flexeril®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: **"Cyclobenzaprine ~~(Flexeril®)~~** Recommended as an option, using a short course (2-3 weeks) of therapy. See Medications for subacute & chronic pain for other preferred options. Cyclobenzaprine ~~(Flexeril®)~~ is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. (Kinkade, 2007) Metabolism CYP 4501A2, 3A4. T ½ B = 18hr, 32 hour for ER dose form."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability. Morover, DWC **disagrees** with commenter's suggested edits as they do not substantively improve the guideline language. Nevertheless, through ODG's internal evidence evaluation review process, ODG ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "Cyclobenzaprine (Flexeril®)." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. Further, the reference to "subacute" pain was removed pursuant to DWC's decision to insure that the guidelines apply to chronic only.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Cyclobenzaprine (Flexeril®)*** has been modified as follows: **"Cyclobenzaprine (Flexeril®)** "Recommended as an option, using a short course of therapy. See Medications for ~~subacute &~~ chronic pain for other preferred options. Cyclobenzaprine (Flexeril®) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. (Clinical Pharmacology, 2008) Cyclobenzaprine-treated patients with

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. (Kinkade, 2007) Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by Ortho McNeil Pharmaceutical."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Cyclobenzaprine (Flexeril®)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended as an option, using a short course of therapy."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment	Commenter states that both guidelines do not recommend the use of ***Cytokine DNA Testing for Pain***.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Comment does not address the substance of the proposed regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines Part 2. Pain Intervention and Treatments ***Cytokine DNA Testing for Pain [DWC]***			Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "cytokine" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Cytokine DNA Testing for Pain [DWC]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Detoxification***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Detoxification*** for the treatment of chronic pain. Commenter states that the treatment is recommended "as indicated below." Commenter makes no reference to the discussion below. Commenter adds that the ACOEM Chronic Pain Update also recommends ***Detoxification***. He indicates that the guideline contains a long discussion under this recommendation.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Comment does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "detoxification" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter agrees with this guideline. Commenter, however, appears to recommend leaving out the citation and reference to Rapid detox.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part. Agree** with comment accepting DWC's guideline. **Disagree** with comment recommending removing citations and references. See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Detoxification			Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Detoxification***	Commenter references the Cannabinoids treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: Recommended by a certified chemical dependency professional (MD/DO) as indicated below. Detoxification is defined as withdrawing a person from a specific psychoactive substance, and it does not imply a diagnosis of addiction, abuse or misuse. May be necessary due to the following: (1) Intolerable side effects, (2) Lack of response, (3) Aberrant drug behaviors as related to abuse ~~and~~ dependence or trafficking/diversion, (4) refractory comorbid psychiatric illness, or (5) Lack of functional improvement. Gradual weaning is recommended for long-term opioid users because opioids cannot be abruptly discontinued without probable risk of withdrawal symptoms. (Benzon, 2005) See also Rapid detox.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Drug Testing***	Commenter references the ***Drug Testing*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: **~~Drug testing~~ Clinical Urine Drug Testing (CUDT) –UPLC – MS/MS** Recommended ~~as an option~~ when using controlled substances (ex: opioids), using a urine drug screen (is	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	only presumptive, many false negatives and false positives should be reflexed with confirmatory LC/MS/MS) to assess for the use or the presence of prescribed medications or illegal drugs. For more information, see Opioids, criteria for use: (2) Steps to Take Before a Therapeutic Trial of Opioids & (4) On-Going Management; Opioids, differentiation: dependence & addiction; Opioids, screening for risk of addiction (tests); & Opioids, steps to avoid misuse/addiction.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Drug Testing***	Commenter references the ***Drug Testing*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines, but offers no recommendation.	Theodore Blatt, M.D. Medical Director Anthem Blue Cross July 28, 2008	**Disagree.** The comment does not substantively address the proposed changes to the current medical treatment utilization schedule regulations.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Duloxetine (Cymbalta®)***	Commenter references the ***Duloxetine (Cymbalta®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: Recommended as a first-line treatment option in neuropathic pain. Duloxetine (Cymbalta®) is a norepinephrine and serotonin reuptake inhibitor antidepressant. It has FDA approval for treatment of depression, fibromyalgia, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). The starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. The medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily.	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** ODG, through its internal evidence evaluation review process has conducted its own evidence-base review, and has updated the individual treatment guideline on "Duloxetine (Cymbalta®)." The update individual treatment guideline includes commenter's suggestion that the guideline includes the reference to "fibromyalgia." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. However, DWC **disagrees** with commenter's remaining suggested edits as they do not substantively improve the guideline language.	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Duloxetine (Cymbalta®)***, has been modified as follows: **"Duloxetine (Cymbalta®)** "Recommended as an option in first-line treatment option in neuropathic pain. Duloxetine (Cymbalta®) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(Arnold, 2005) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. Note: On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with hepatic insufficiency. See also Antidepressants for neuropathic pain. A CYP 450 1A2 2D6 inhibiter.			and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). The starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. The medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. Note: On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta. Postmarketing

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with hepatic insufficiency. See also Antidepressants for ~~neuropathic~~ chronic pain for general guidelines, as well as specific Duloxetine listing for more information and references. On June 13, 2008, the FDA approved a new indication for duloxetine HCl delayed-release capsules (Cymbalta®; Eli Lilly and Company) for the management of fibromyalgia in adults. The FDA notes that although duloxetine was effective for reducing pain in patients with and without major depressive disorder, the degree of pain relief may have been greater in those

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				with comorbid depression. Treatment of fibromyalgia with duloxetine should be initiated at 30 mg/day for 1 week and then uptitrated to the recommended 60-mg dose. (Waknine, 2008) Note: This drug was recently included in a list of 20 medications identified by the FDA's Adverse Event Reporting System, that are under FDA investigation. (FDA, 2008)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Duloxetine (Cymbalta®)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended as a first-line treatment option in neuropathic pain."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Education***	Commenter references the ***Education*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended. Ongoing ~~E~~education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of all chronic pain patients. Currently, practitioners often think of education last, after medications, manual therapy and surgery. Practitioners and insurers must develop and implement an effective ongoing strategy and skills to educate patients, employers, insurance systems, policy	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** with the commenter that ongoing education of the patient and family, as well as the employer insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain. Thus, the individual treatment guideline for ***Education*** of the Chronic Pain Medical Treatment Guidelines will be modified to reflect commenter's suggested language. The remaining revised language in the guideline reflects updates by ODG in the revised version dated October 23,	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Education,*** has been modified as follows: **"Education** "Recommended. On-going ~~E~~education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	makers and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient and family. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention. (Colorado, 2002) Goal assessment and evaluation should be provided with each visit/treatment."		2008. **Disagree** with commenter's remaining suggested edits as they do not substantively improve the guideline language.	emphasis in the treatment of chronic pain. Currently, practitioners often think of education last, after medications, manual therapy and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention. (Colorado, 2002) An educational technique known as the Alexander technique, along with exercise, is effective for long-term relief of chronic low back pain, according to the results of a randomized

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				trial reported in the *BMJ*. Lessons in the Alexander technique offer an individualized approach designed to develop lifelong skills for self-care that help people avoid poor habits affecting posture and neuromuscular coordination. An accompanying editorial notes that the results of this study may not apply to clinical practice. In addition, in the US there are few instructors trained in this technique. (Little, 2008)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Education***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Education***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Education*** in connection with the treatment of chronic pain. Commenter observes that discussion is 10 lines. Commenter adds that the ACOEM Chronic Pain Update also recommends ***Education*** in connection with the treatment of chronic pain. Commenter observes that discussion is extremely detailed.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Comment does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "education" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	None.
9792.24.2(a)	Commenter makes reference to proposed section	Jeffrey S. Harris,	**Agree in part. Agree** that	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Epidural steroid injections (ESIs)***	9792.24.2(d), which states that "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline shall apply." Commenter agrees with the intent of the proposed regulations to address conflict with body part chapters in the MTUS by deferring to the relevant body part chapter to avoid contradictory advice. Commenter opines that this is an excellent concept and should avoid confusion and disputes. Commenter opines that this should be applied to Epidural steroid injections (p. 31), by deleting this topic from the chronic pain medical treatment guidelines.	M.D. August 11, 2008	proposed section 9792.24.2(d) is intended to avoid internal conflict in the MTUS, "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline" applies. **Disagree** with the suggestion to remove the individual topic guideline of "epidural steroid injections (ESIs)" from the chronic pain medical treatment guidelines. After the condition has been determined to be chronic and the injured worker is receiving treatment under the chronic pain medical treatment guidelines, it is appropriate for that injured worker to continue to receive treatment under that guideline, including "epidural steroid injections (ESIs)" which are available under the chronic pain guidelines. This avoids internal conflict in the MTUS and ensures provision of continuous effective medical treatment without interruption.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Epidural steroid***	Commenter references the ***Epidural steroid injections (ESIs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language. Nevertheless, through ODG's own internal-evidence evaluation review process, ODG has conducted its own evidence-base review, and has updated the	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Epidural steroid injections (ESIs),*** has been modified as follows:

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
injections (ESIs)	corroborative findings of radiculopathy). See specific criteria for use below. Most current guidelines recommend no more than 2 ESI injections (consider under c-arm guidance). This is in contradiction to previous generally cited recommendations for a "series of three" ESIs. These early recommendations were primarily based on anecdotal evidence. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Current recommendations suggest a second epidural injection if partial measurable success is produced with the first injection and a third ESI is rarely recommended. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts with a motivated patient, including continuing a home daily exercise program. There is little information on improved function. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) See also Epidural steroid injections, "series of three".		individual treatment guideline on "Epidural steroid injections (ESIs)." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	**"Epidural steroid injections (ESIs)** "Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). See specific criteria for use below. Most current guidelines recommend no more than 2 ESI injections. This is in contradiction to previous generally cited recommendations for a "series of three" ESIs. These early recommendations were primarily based on anecdotal evidence. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Current recommendations suggest a second epidural injection if partial success is produced with the first injection, and a third ESI is rarely recommended. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function. The

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) See also Epidural steroid injections, "series of three". **Criteria for the use of Epidural steroid injections:** *Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.* 1) Radiculopathy must be documented by physical examination <u>and</u> corroborated by imaging studies and/or

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should ~~only~~ be based on continued objective documented pain and functional improvement, including ~~offered if there is~~ at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				(CMS, 2004) (Boswell, 2007) ~~8) Repeat injections should be based on continued objective documented pain and function response.~~ ~~9~~8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Epidural steroid injections (ESIs)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy." In reference to the end of the last sentence in paragraph one which, in relevant part states: "… [T]here is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain." Commenter states that a specific recommendation should be made about the use or no use of ESI for cervical radiculopathy.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter states that although CCA agrees that exercise is appropriate for most chronic conditions, some patients cannot exercise for many reasons, e.g., heart and lung issues, fractures and acute severe tears of various soft tissues. Commenter is concerned that the MTUS language will penalize doctors who do not recommend exercise for every patient, even if it is not	David Benevento, DC, President California Chiropractic Association August 12, 2008	**Disagree.** Whether or not to prescribe exercise is a clinical decision. A treating physician is in the best position to determine whether or not the patient is capable of following an exercise program.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Exercise	clinically recommended. Commenter requests that the medical treatment guideline for exercise be deleted from the guidelines as inappropriate treatment. Commenter requests that the DWC amend the medical treatment guideline for ***Exercise*** in the chronic pain medical treatment guidelines at p. 32, as reflected below: **"**Exercise-Recommended. There is strong evidence that exercise programs, including aerobic conditioning and strengthening are superior to treatment programs that do not include exercise. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen. A therapeutic exercise program should be initiated at the start of any treatment ***or*** rehabilitation ***program, unless exercise is contraindicated***...."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Exercise***	Commenter references the ***Exercise*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "A daily therapeutic exercise program should be initiated at the start of any treatment rehabilitation."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language. Nevertheless, through ODG's internal evidence evaluation review process, ODG has updated it's guideline on this individual treatment topic. DWC has adapted this guideline into its chronic pain medical treatment guidelines.	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Exercise***, has been modified as follows: **"Exercise** "Recommended. There is strong evidence that exercise programs, including aerobic conditioning and strengthening, are superior to treatment programs that do not include exercise. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				exercise regimen. A therapeutic exercise program should be initiated at the start of any treatment or rehabilitation program, unless exercise is contraindicated. Such programs should emphasize education, independence, and the importance of an on-going exercise regime. (State, 2002) (Airaksinen, 2006) A recent study of the long term impact of aerobic exercise on musculoskeletal pain, in a prospective cohort of 866 healthy seniors followed for 14 years, found that exercise was associated with a substantial and significant reduction in pain even after adjusting for gender, baseline BMI and attrition, and despite the fact that fractures, a significant predictor of pain, were slightly more common among exercisers. (Bruce, 2005) A recent trial concluded that active physical treatment, cognitive-behavioral treatment, and the two combined each resulted in equally significant improvement, much better compared to no treatment. (The cognitive treatment

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				focused on encouraging increased physical activity.) (Smeets, 2006) Progressive walking, simple strength training, and stretching improved functional status, key symptoms, and self-efficacy in patients with fibromyalgia. (Rooks, 2007) Physical conditioning in chronic pain patients can have immediate and long-term benefits, according to a low-quality study presented at the American Academy of Pain Medicine 24th Annual Meeting. (Burleson, 2008) Physical therapy in warm-water has been effective and highly recommended in persons with fibromyalgia. In this RCT, an aquatic exercise program including one-hour, supervised, water-based exercise sessions, three times per week for 8 months, was found to be cost-effective in terms of both health care costs and societal costs. (Gusi, 2008) An educational technique known as the Alexander technique, along with exercise, is effective for long-term relief of chronic low back pain, according to the results of a randomized trial reported in the BMJ.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				(Little, 2008)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Exercise***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Exercise***, but the discussion is ½ a page. Commenter adds that the ACOEM Chronic Pain Update recommends ***Exercise***. He indicates that the section has 18 recommendations in 15 pages, which contain 6 subcategories.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Comment does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "exercise" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Exercise***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Fioricet***	Commenter recommends avoiding use of ***Fioricet***.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language. The guideline refers to another section which addresses commenter's concerns.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Flexeril®**	Commenter recommends removal of the **Flexeril®** reference before and after (Cyclobenzaprine).	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
(Cyclobenzaprine)				
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Functional imaging of brain responses to pain [DWC]**	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not Recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Functional restoration programs (FRPs)***	Commenter quotes the introductory sentence in the DWC Chronic Pain Medical Treatment Guidelines on the ***Functional restoration programs***, which states as follows: "Recommended, although research is still ongoing as to how to most appropriately screen for inclusion in these programs." Commenter then questions whether the sentence means that it will be recommended if an appropriate screen is developed and used. Commenter adds that the ACOEM Chronic Pain Update recommendation on ***Functional restoration programs c***onsists of 3 pages, with 2 recommendations. Commenter adds that the recommendation is based upon 2 RCTs, 2 systemic reviews, 1 review, 2 low quality RCTs, and 1 other study.	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Commenter expresses concern about whether under this guideline an appropriate screen will be developed in the future to select patients for functional restoration programs. If the screen is developed in the future, the screen will be considered in the future. With regard to the remaining comments, they do not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "functional restoration programs (FRPs)" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all but the following language: Recommended. These	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments **Functional restoration programs (FRPs)**	programs emphasize the importance of function over the elimination of pain. FRPs incorporate components of exercise progression with disability management and psychosocial intervention.		Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Gabapentin (Neurontin®)**	Commenter recommends removal of the **(Neurontin®)** reference after Gabapentin.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** with commenter's suggestion to remove the brand name of the drug. DWC agrees with ODG's practice that while major listings use generic names, ODG also includes brand names for usability.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Galvanic Stimulation**	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not Recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Glucosamine (and Chondroitin Sulfate) [DWC]***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not recommend ***Glucosamine*** in connection with the treatment of chronic pain. Commenter observes that discussion is 4 lines. Commenter adds that the ACOEM Chronic Pain Update also recommends ***Glucosamine*** in connection with the treatment of chronic pain. Commenter observes that discussion is half page.	James E. Lessenger, M.D. August 4, 2008	**Agree in part.** DWC is not evaluating ACOEM's Glucosamine guideline. Originally, Glucosamine was characterized in Appendix A as "herbal and nutritional supplement." (See, Appendix A, p. 15.) New "[s]tudies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments ***Glucosamine (and Chondroitin Sulfate)***, is amended as follows: **"Glucosamine (and Chondroitin Sulfate) ~~[DWC]~~** ~~Glucosamine (and Chondroitin Sulfate) is not~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007)" (See, Revised DWC Proposed Chronic Pain Medical Tratment Guidelines, p. 51.) Because of this purified form, clinical application is more likely to be efficatious as supported by the scientific evidence. Thus, ODG has conducted a further evidence-based review that includes the recent research. ODG has revised its Glucosamine (and Chondroitin Sulfate) guideline, and DWC proposes to adapt its revised guideline.	~~recommended for chronic pain.~~ Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, doubleblind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. (Reginster, 2001) Another RCT with 202 patients concluded that long-term treatment with glucosamine sulfate retarded the progression of knee osteoarthritis, possibly determining disease

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				modification. (Pavelka, 2002) The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. [Note: The GAIT investigators did not use glucosamine sulfate (GS).] (Distler, 2006) Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. (Clegg, 2006) In a recent meta-analysis, the authors found that the apparent benefits of chondroitin were largely confined to studies of poor methodological quality, such as those with small patient numbers or ones with unclear concealment of allocation. When the analysis was limited to the three best-designed studies with the largest sample sizes (40% of

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				all patients), chondroitin offered virtually no relief from joint pain. While not particularly effective, chondroitin use did not appear to be harmful either, according to a meta-analysis of 12 of the studies. (Reichenbach, 2007) Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. Differences in results originate from the differences in products, study design and study populations. Symptomatic efficacy described in multiple studies performed with glucosamine sulphate (GS) support continued consideration in the OA therapeutic armamentarium. Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				the tablets. (Reginster, 2007) [Note: DONA™ Glucosamine Sulfate is the original crystalline glucosamine sulfate (GS), which was first developed and marketed for human use by Rotta Research Laboratorium, funding some of the initial trials. Glucosamine hydrochloride (GH) is not proprietary, so it tends to be less expensive but there has also been less funding for quality studies.] *Recent research:* This RCT assessed radiographic outcomes in OA of the knee in patients being treated with glucosamine hydrochloride (note: GH not GS), chondroitin sulfate (CS), glucosamine plus CS, celecoxib, or placebo. Over 2 years, no treatment achieved the predefined clinically important difference from placebo in terms of joint space width (JSW) loss. The effect of the combination of glucosamine plus CS may be less active than the effect of each treatment singly. Kellgren/Lawrence (K/L) grade 2 knees may represent a more potentially responsive population. Treatment effects on K/L

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				grade 2 knees (less severe OA), but not on K/L grade 3 knees (more severe), showed a trend toward improvement relative to the placebo group. (Sawitzke, 2008)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Glucosamine (and Chondroitin Sulfate) [DWC]***	Commenter states that arthritis treatment is not properly addressed in the DWC Chronic Pain Medical Treatment Guidelines (page 41). Commenter adds that the few places it is addressed, it is handled erroneously (e.g., page 34, Glucosamine). Commenter indicates that there are now at least two quality RCTs showing delayed progression of destructive joints with this intervention. (Pavelká 02, Reginster 03)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part.** See response submitted in connection with comment submitted by James E. Lessenger, M.D., dated August 4, 2008, on section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Glucosamine (and Chondroitin Sulfate) [DWC], above. It is noted that the comment was submitted under the individual treatment guideline topic of "Medications for subacute & chronic pain" and referenced arthritis treatments, but the substance of the comment related to the individual treatment guideline topic of Glucosamine (and Chondroitin Sulfate) [DWC].	See action taken in connection with comment submitted by James E. Lessenger, M.D., dated August 4, 2008, on section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Glucosamine (and Chondroitin Sulfate) [DWC], above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Green Tea and Herbal Medicines**	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter references DWC's Green Tea and Herbal Medicines guidelines. Commenter states that it is critical for the MTUS to address the issue of "non-medical treatment" (homeopathic) from medical treatment. Commenter states that clearly this is non-medical treatment and that the Labor Code defines that "medical treatment" be provided. Commenter adds that this is a significant issue in the community of these non-medical treatments being dispensed, compounded and charged	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	for. Commenter states that clarification would be most beneficial to the user of the MTUS regarding this issue.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Home health services**	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended only for otherwise recommended medical treatment for patients who are homebound, on a part-time or "intermittent" basis."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Hydrocodone (Vicodin®, Lortab®)***	Commenter references the ***Hydrocodone (Vicodin®, Lortab®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: **Hydrocodone ~~(Vicodin®, Lortab®)~~(Acetaminophen combinations)** See Opioids (avoid immediate release use)	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability. Moreover, **disagree** with commenter's remaining suggested edits as they do not substantively improve the guideline language. Nevertheless, through ODG's internal evidence evaluation review process, ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "Hydrocodone (Vicodin®, Lortab®)." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Hydrocodone (Vicodin®, Lortab®)***, has been amended as follows: **"Hydrocodone (Vicodin®, Lortab®)** "Hydrocodone ~~or~~ is a semi-synthetic opioid which is considered the most potent oral opioid that does not require special documentation for prescribing in some states (not including California). See Opioids."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Implantable drug-delivery systems*** Commenter quotes the guidelines as follows: "Recommended only	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Comment does not address the substance of the proposed regulations. Commenter's comparison between	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments ***Implantable drug-delivery systems (IDDSs)***	as an end-stage treatment alternative for selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods and following a successful temporary trial." Commenter adds that the ACOEM Chronic Pain Update does not recommend ***Implantable drug-delivery systems***, and indicates that the subject is covered in chapter 12.		ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "implantable drug-delivery systems (IDDSs)" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Implantable drug-delivery systems (IDDSs)***	Commenter references the ***Implantable drug-delivery systems (IDDSs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended only as an end-stage treatment alternative for well selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial (note: 30% placebo response rate). Results of studies of opioids for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of opioids for severe cases, not to exceed 2 weeks, and do not support chronic use (for which a pump would be used), although IDDSs may be appropriate in selected cases of chronic, severe low back pain or failed back syndrome. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) For most patients, it should be used as part of a program to facilitate restoration of function and return to activity, less or lower opioid utilization and not just for pain reduction."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language. Nevertheless, through ODG's internal evidence evaluation review process, ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "Implantable drug-delivery systems (IDDSs)." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	9792.24.2(a), Chronic Pain Medical, Treatment Guidelines Part 2. Pain Intervention and Treatments, ***Implantable drug-delivery systems (IDDSs)*** has been amended as follows: **"Implantable drug-delivery systems (IDDSs)** "Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial. Results of studies of opioids for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of opioids for severe cases, not to exceed 2 weeks, and do not support chronic use (for

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter continues to edit the treatment guideline, in relevant part, as follows: • Used for the treatment of malignant (cancerous) pain and all of the following criteria are met: 1. ~~Strong~~ Schedule II CCH opioids or other analgesics in adequate doses, with fixed schedule ~~(not PRN)~~ and PRN for severe episode dosing, have failed to relieve pain or intolerable side effects to systemic opioids or other analgesics have developed; and 2. Life expectancy is greater than 3 months (less invasive techniques such as external infusion pumps provide comparable pain relief in the short term and are consistent with standard of care); and 3. Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and 4. No contraindications to implantation exist such as sepsis or coagulopathy; and 5. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by a 50% reduction in pain. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met. • Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met: 1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (comprehensive pharmacologic, surgical, psychologic or physical), if appropriate and not contraindicated; and. . .”			which a pump would be used), although IDDSs may be appropriate in selected cases of chronic, severe low back pain or failed back syndrome. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) For most patients, it should be used as part of a program to facilitate restoration of function and return to activity, and not just for pain reduction. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50% reduction

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				in pain. (Tutak, 1996) (Yoshida, 1996) (BlueCross, 2005) (United Health Care, 2005) See also Opioids ~~and the Low Back Chapter~~. In a study of IDDS in 136 patients with low back pain, after one year 87% of the patients described their quality of life as fair to excellent, and 87% said they would repeat the implant procedure. However, complication rates (i.e., infection, dislodging, and cerebrospinal fluid leak) are likely to rise with time in these procedures and more longitudinal outcome studies need to be conducted. (Deer, 2004) In one survey involving 429 patients with nonmalignant pain treated with intrathecal therapy, physician reports of global pain relief scores were excellent in 52.4% of patients, good in 42.9%, and poor in 4.8%. In another study of 120 patients, the mean pain intensity score had fallen from 93.6 to 30.5 six months after initiation of therapy. In both studies, patients reported significant improvement in activities of daily living, quality of life measures, and satisfaction

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				with the therapy. Constipation, urinary retention, nausea, vomiting, and pruritus are typical early adverse effects of intrathecal morphine and are readily managed symptomatically. Other potential adverse effects include amenorrhea, loss of libido, edema, respiratory depression, and technical issues with the intrathecal system. (Winkelmuller, 1996) (Paice, 1997) One study in patients suffering from chronic low back pain caused by failed back syndrome found a 27% improvement after 5 years for patients in the intrathecal drug therapy group, compared with a 12% improvement in the control group. (Kumar, 2002) Supporting empirical evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				subsequent treatment. Generally, use of implantable pumps is FDA approved and indicated for chronic intractable pain. Treatment conditions may include FBSS, CRPS, Arachnoiditis, Diffuse Cancer Pain, Osteoporosis, and Axial Somatic Pain. As we have gained more experience with this therapy, it has become apparent that even intrathecal opiates, when administered in the long term, can be associated with problems such as tolerance, hyperalgesia, and other side effects. Consequently, long-term efficacy has not been convincingly proven. However, it is important to note that there is a distinction between "tolerance" and "addiction", and the levels of drugs administered intrathecally should be significantly below what might be needed orally in their absence. (Osenbach, 2001) (BlueCross BlueShield, 2005) See also Intrathecal drug delivery systems, medications "*Refills:* IDDSs dispense

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription. (Hassenbusch, 2004) **"Indications for Implantable drug-delivery systems:** Implantable infusion pumps are considered medically necessary when used to deliver drugs for the treatment of: o Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents); o Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				of chemotherapeutic agents); o Head/neck cancers (intra-arterial injection of chemotherapeutic agents); o Severe, refractory spasticity of cerebral or spinal cord origin in patients who are unresponsive to or cannot tolerate oral baclofen (Lioresal®) therapy (intrathecal injection of baclofen) "Permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opiates or non-opiate analgesics, in the treatment of chronic intractable pain, are considered medically necessary when: "• Used for the treatment of malignant (cancerous) pain and all of the following criteria are met: "1. Strong opioids or other analgesics in adequate doses, with fixed schedule (not PRN) dosing, have failed to relieve pain or intolerable side effects to systemic opioids or other analgesics have developed; and "2. Life expectancy is greater than 3 months (less invasive techniques such as external infusion pumps provide comparable pain relief in the

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				short term and are consistent with standard of care); and "3. Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and "4. No contraindications to implantation exist such as sepsis or coagulopathy; and "5. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by a 50% reduction in pain. A *temporary* trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met. "• Used for the treatment of <u>non-malignant (non-cancerous)</u> pain with a duration of greater than 6 months and all of the following criteria are met: "1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, surgical, psychologic or physical), if appropriate and not contraindicated; and "2. Intractable pain secondary to a disease state with objective

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				documentation of pathology in the medical record; and "3. Further surgical intervention or other treatment is not indicated or likely to be effective; and "4. Psychological evaluation has been obtained and evaluation states that the pain is not primarily psychologic in origin and that benefit would occur with implantation despite any psychiatric comorbidity; and "5. No contraindications to implantation exist such as sepsis or coagulopathy; and "6. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by at least a 50% to 70% reduction in pain and documentation in the medical record of ~~improved~~ functional improvement and associated reduction in oral pain medication use. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-5 above are met."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all but the following language:	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments ***Implantable drug-delivery systems (IDDSs)***	"Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial although IDDSs may be appropriate in selected cases of chronic, severe low back pain or failed back syndrome. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50% reduction in pain. Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met: 1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, surgical, psychologic or physical), if appropriate and not contraindicated; and 2. Intractable pain secondary to a disease state with objective documentation of pathology in the medical record; and 3. Further surgical intervention is not indicated; and 4. Psychological evaluation has been obtained and evaluation states that the pain is not primarily psychologic in origin and that benefit would occur with implantation despite any psychiatric comorbidity; and 5. No contraindications to implantation exist such as sepsis or coagulopathy; and		Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	6. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by at least a 50% to 70% reduction in pain and documentation in the medical record of improved function and associated reduction in oral pain medication use. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-5 above are met." Commenter believes it is critical to include in the MTUS item No. 6 above, and this should not be combined with the other indications which are not found in the injured worker population.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Intrathecal drug delivery systems, medications***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Intrathecal drug delivery systems***. Commenter states that the recommendation lists three stages: 1st stage: Morphine including a non-FDA approved medication, 2nd stage using clonidine (no reference is given for this), and 3rd Baclofen (cites recommendations from a consensus conference and articles from a non-peer reviewed journal). Commenter adds that the ACOEM Chronic Pain Update does not recommend ***Intrathecal drug delivery systems***, and indicates, and that "no recommendation" is based upon 2 high quality RCTs, 3 systemic reviews, 5 reviews, 17 other studies. The recommendation contains no consensus data. Commenter further adds that Baclofen contains a guideline of "No recommendation," and that the section cites high grade crossover trial that was equivocal.	James E. Lessenger, M.D. August 4, 2008	**Agree in part.** ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "Intrathecal drug delivery systems, medications." ODG added appropriate references and citations from peer-reviewed sources. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. DWC **disagrees** with the remaing comments as they do not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "intrathecal drug delivery systems (IDDSs)" is not clear as it does not address the substance of the	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Intrathecal drug delivery systems, medications,*** has been modified as follows: **"Intrathecal drug delivery systems, medications** "Recommended as indicated below. ~~(The following recommendations were made prior to FDA approval of ziconotide.) (Hassenbusch, 2004)~~ *Recommended 1st stage:* Morphine is generally the initial IDDS medication. The maximum recommended dose for this drug is 15 mg/day with a concentration

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			guideline, and commenter offers no substantive suggestion to improve the guideline.	of ~~3~~20 mg/mL. An alternative non-FDA approved medication is hydromorphone. The maximum recommended dose for this medication is ~~10~~ 4 mg/day with a concentration of ~~3~~10 mg/mL. Other opioids (including Fentanyl and Sufentanil) have been used for intrathecal chronic non-malignant pain but are non-FDA approved and have little research associated with their use. (Waara-Wolleat, 2006) (Deer, 2007) The previous 2003 Polyanalgesic conference recommended a maximum dose of intrathecal morphine at 15 mg/day with a maximum concentration of 30 mg/mL. They also recommended a maximum dose of hydromorphone of 10 mg/day with a concentration of 30 mg/mL. (Hassenbusch, 2004) It can be seen that there has been a substantial decrease in concentration (particularly for hydromorphone). The newer maximum concentrations were recommended, in part, to prevent granulomas. *Recommended 2nd stage*: If

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				side effects occur, an upper limit of dosing is reached, or neuropathic pain is present, clonidine is next recommended as an addition to an opioid (maximum recommended dose of 1 mg/day and a concentration of 2 mg/mL). Bupivacaine has also been recommended as an alternative to clonidine (maximum dose of 30 mg/day and a concentration of ~~38~~ 40 mg/mL). Clonidine, which is FDA approved for intrathecal delivery, is thought to provide analgesic effect via a non-opioid mechanism. It has been found to offer only short-term relief when used as a single agent. (Deer, 2007) *Recommended 3rd stage:* The recommendation has been made to add both clonidine and bupivacaine. Baclofen has been used to treat intractable spasticity from brain injury, cerebral palsy, and spinal cord injury and has resulted in improvement in muscle tone and pain relief. (Guillaume, 2005) See also Ziconotide (Prialt®)~~.~~, which is ~~R~~recommended after documentation of a failure of a trial of intrathecal

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				morphine and hydromorphone (Dilaudid). The 2007 Polyanalgesic Consensus Conference Recommendations for the Management of Pain by Intrathecal Drug Delivery concluded that ziconotide should be updated to a first-line intrathecal drug.~~)~~ This recommendation was published in a ~~non-peer reviewed~~ journal not yet accepted for inclusion in MEDLINE and the conference was sponsored by Elan Pharmaceuticals. (Deer, 2007)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Intrathecal drug delivery systems, medications***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all but the following language and combining this section with the IDDS: "Recommended 1st stage: Morphine is generally the initial IDDS medication Recommended 2nd stage: clonidine is next recommended as an addition to an opioid Recommended 3rd stage: The recommendation has been made to add both clonidine and bupivacaine."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain	Commenter states that the discussion in the ***Intravenous regional sympathetic blocks*** section of the DWC Chronic Pain Medical Treatment Guidelines uses the term "RSD" which is a discarded term by over 10 years. Commenter adds that the guidelines	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part. Agree** that the term complex regional pain syndrome (CRPS) should be added to the title of the individual treatment guideline topic section. Thus, the	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines Part 2, Pain Intervention and Treatments, ***Intravenous***

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Intervention and Treatments ***Intravenous regional sympathetic blocks (for RSD, nerve blocks) [DWC]***	state these blocks are not commonly done for RSD, which is incorrect. Commenter adds that the section does not state the diagnosis to which the recommendation applies (it seems to infer it only applies to CRPS patients, but that is unclear, and as noted previously is a major systematic issue). Commenter also states that the guidelines state that there is "no scientific evidence to support this treatment, it is recommended as an option." Commenter offers, however, that there are six (6) quality randomized controlled trials and four (4) (67.7%) of these appear to have been omitted from the draft document. Commenter identifies the studies as follows: Livingstone 02; Jadad 95; Ramamarthy 95; Blanchard 90; Hord 92; Taskaynatan 04. Commenter states that these studies would result in a more appropriate "*recommended as indicated below*". Commenter references page 38, par 4 of the DWC Chronic Pain Medical Treatment Guidelines.		guideline is now entitled: "Intravenous regional sympathetic blocks (for RSD/CRPS, nerve blocks)." This new title represents the current terminology associated with these disorders. **Disagree** that the term "reflex sympathetic dystrophy (RSD)" is a "discarded term" as it remains in use by some practitioners who are treating these pain disorders. ODG, however, has conducted its own evidence-based review, and has updated its individual treatment topic guideline on "Intravenous regional sympathetic blocks (for RSD/CRPS, nerve blocks)." DWC **agrees** with the updated version dated October 23, 2008, and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment guidelines. Thus, the guideline developed by DWC is no longer necessary. The entire revised guideline is set forth in the action column of this chart for the benefit of the regulated public.	***regional sympathetic blocks (for RSD, nerve blocks) [DWC]***, has been modified as follows: **"Intravenous regional sympathetic blocks (for RSD/CRPS, nerve blocks) ~~[DWC]~~** "Not recommended, except as indicated below when other treatments are contraindicated. ~~However, if other treatments are contraindicated (e.g. when a stellate ganglion block cannot be done due to bleeding diasthesis) intravenous regional blocks may be performed. IV regional blocks, also known as Bier blocks, are not commonly done for RSD~~ For detailed recommendations by type of block, see Regional sympathetic blocks (stellate ganglion block, thoracic sympathetic block, & lumbar sympathetic block). One meta-analysis found that no significant difference was found between guanethidine and placebo on any of the outcome measures and in one case the trial was stopped prematurely because of the severity of the adverse

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				effects. (Jadad, 1995). Another randomized controlled trial of 32 patients found that IV clodronate is better than placebo and induces lasting improvement of RSD/CRPS. (Varenna, 2000) A randomized controlled trial using guanethidine found that guanethidine was no better than the placebo in improving pain scores in RSD/CRPS. (Ramamurthy, 1995) Since there is a trial suggesting benefit from intravenous regional sympathetic blocks, while not recommended, if other treatments are contraindicated (e.g. when a stellate ganglion block cannot be done due to bleeding diasthesis), intravenous regional blocks may be performed. IV regional blocks, also known as Bier blocks, are not commonly done for RSD/CRPS. Although there is ~~no~~ very limited scientific evidence to support this treatment, it is recommended as an option in certain cases when there are no other alternatives. When the procedure is performed, it must be done in conjunction

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				with a rehabilitation program. There is no role for intravenous regional sympathetic blocks for the diagnosis of RSD/CRPS. (Ramamurthy2, 1995) (Jadad2, 1995)."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Intravenous regional sympathetic blocks (for RSD, nerve blocks)[DWC]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first two sentences, "Not recommended. However, if other treatments are contraindicated (e.g., when a stellate ganglion block cannot be done due to bleeding diasthesis) intravenous regional blocks may be performed."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Ketamine [DWC]***	Commenter states that in the ***Ketamine*** treatment recommendation of the DWC Chronic Pain Medical Treatment Guidelines there is a statement included in the draft which states: "There are no quality studies that support the use of ketamine for chronic pain [sic]." Commenter states that in fact, there are two (2) *high* quality randomized controlled trials on Ketamine (Kvarnstrom 03 & 04). Commenter references the DWC Chronic Pain Medical Treatment Guidelines at page 38, par 5.	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree.** ODG has conducted its own evidence-based review, and has updated its individual treatment topic guideline on "Ketamine." The updated guideline contains the literature citations referenced by the commenter. DWC **agrees** with the updated version of ODG's individual treatment topic guideline on "Ketamine" dated October 23, 2008, and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment guidelines. Thus, the guideline developed by DWC is no longer necessary. The entire revised guideline is set forth in the	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Ketamine [DWC]***, has been modified as follows: "**Ketamine ~~[DWC]~~** Not recommended. There is insufficient evidence to support the use of ketamine for the treatment of chronic pain. There are no quality studies that support the use of ketamine for chronic pain, but it is under study for

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			action column of this chart for the benefit of the regulated public.	CRPS. (Goldberg2, 2005) (Grant, 1981) (Rabben, 1999) Ketamine is an anesthetic in animals and humans, and also a drug of abuse in humans, but ketamine may offer a promising therapeutic option in the treatment of appropriately selected patients with intractable CRPS. More study is needed to further establish the safety and efficacy of this drug. (Correll, 2004) One very small study concluded that ketamine showed a significant analgesic effect on peripheral neuropathic pain, but the clinical usefulness is limited by disturbing side effects. Another study by the same author with a sample size too small for ODG (10) concluded that ketamine showed a significant analgesic effect in patients with neuropathic pain after spinal cord injury, but ketamine was associated with frequent side effects. (Kvarnström, 2003-4)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Intervention and Treatments ***Ketamine [DWC]***			Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Ketoprofen***	Commenter points out that this medication is available over the counter.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits do not substantively improve the guideline language.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Lamotrigine (Lamictal®)***	Commenter recommends removal of the ***(Lamictal®)*** reference after Lamotrigine.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Levetiracetam (Keppra®)***	Commenter recommends removal of the ***(Keppra®)*** reference after Levetiracetam.	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** DWC **disagrees** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not recommend ***Low-Level Laser Therapy***, and observes that the guidelines cite 9 references. Commenter adds that the ACOEM Chronic Pain Update does not recommend ***Low-Level Laser Therapy***, and indicates that the guideline contains two recommendations of "not	James E. Lessenger, M.D. August 4, 2008	**Disagree.** Comment does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Low-Level Laser Therapy (LLLT)	recommended." Commenter further observes that the guidelines cite 8 high quality RCTs, 4 systemic reviews, 1 guideline, 3 low grade RCTs, and 1 other study.		"Low-Level Laser Therapy (LLLT)" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Low-Level Laser Therapy (LLLT)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Lumbar sympathetic block***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Recommended as indicated below. Useful for diagnosis and treatment of pain of the pelvis and lower extremity secondary to CRPS-I and II. This block is commonly used for differential diagnosis and is the preferred treatment of sympathetic pain involving the lower extremity."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Lumbar sympathetic block***	Commenter makes reference to proposed section 9792.24.2(d), which states that "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline shall apply." Commenter agrees with the intent of the proposed regulations to address conflict with body part chapters in the MTUS by deferring to the relevant body part chapter to avoid contradictory advice. Commenter opines that this is an excellent concept and should avoid confusion and disputes. Commenter opines that	Jeffrey S. Harris, M.D. August 11, 2008	**Agree in part. Agree** that proposed section 9792.24.2(d) is intended to avoid internal conflict in the MTUS, "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline" applies. **Disagree** with the suggestion to remove the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	this should be applied to Lumbar sympathetic block (p. 39), by deleting this topic from the chronic pain medical treatment guidelines.		individual topic guideline of "lumbar sympathetic block" from the chronic pain medical treatment guidelines. After the condition has been determined to be chronic and the injured worker is receiving treatment under the chronic pain medical treatment guidelines, it is appropriate for that injured worker to continue to receive treatment under that guideline, including "epidural steroid injections (ESIs)" which are available under the chronic pain guidelines. This avoids internal conflict in the MTUS and ensures provision of continuous effective medical treatment without interruption.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Magnet Therapy***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Manual therapy & manipulation***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***manual therapy & manipulation***. Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommend ***manual therapy & manipulation*** for chronic pain if caused by musculoskeletal conditions and manipulation is specifically recommended as an option for acute conditions. He indicates that the guidelines quote the Colorado Guidelines. Commenter also states that the guideline does not give the	James E. Lessenger, M.D. August 4, 2008	**Agree in part. Agree** with the comment that the guidelines do not provide "recommendations for acute conditions." References to acute recommendations will be removed from the individual treatment topic guideline on "Manual therapy & manipulation" based on public comments that it was inappropriate for these	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Manual therapy & manipulation***, has been modified as follows: **"Manual therapy & manipulation**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	recommendations for acute therapy. He further observes that there is no mention of who is going to do the recommending. Commenter opines that this is essentially a meaningless statement. He observes that the guideline is ½ page in length and uses only one reference; the Colorado Guideline. Commenter further opines that this is clearly a political statement. Commenter adds that the ACOEM Chronic Pain Update recommends ***manual therapy & manipulation***. Commenter observes that the recommendation is 8 pages long, it contains 8 recommendations based on 25 RCTs, 14 systemic reviews, 2 guidelines, 10 low quality RCTs, and 1 other study.		guidelines to address acute conditions when the guidelines are intended for chronic conditions. The body part chapters of the MTUS address the acute conditions in the MTUS. Moreover, **agree** that the original guideline did not provide indications for "Manual therapy & manipulation." This has been resolved by the current revised guideline which is being adopted. The indications are now clearly stated. **Disagree** with commenter's comparison of ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "Manual therapy & manipulation." Commenter's intention is not clear as his comments in this regard do not address the substance of the regulations, and offer no substantive suggestion to improve the guideline. ODG has now reviewed the evidence-base, and has updated its individual treatment guideline topic on "manual therapy & manipulation." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment guidelines. This updated	"Recommended for chronic pain if caused by musculoskeletal conditions~~, and manipulation is specifically recommended as an option for acute conditions~~. Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. **"Low back:** Recommended as an option. *Therapeutic care* – Trial of 6 visits over 2 weeks, with evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks. *Elective/maintenance care* – Not medically necessary. *Recurrences/flare-ups* – Need to re-evaluate treatment success, if RTW

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			version addresses commenter's concerns regarding indications.	achieved then 1-2 visits every 4-6 months. **Ankle & Foot:** Not recommended. **Carpal tunnel syndrome:** Not recommended. **Forearm, Wrist, & Hand:** Not recommended. **Knee:** Not recommended. **Treatment Parameters from state guidelines** a. Time to produce ~~objective functional gains~~ effect: ~~3-5~~ 4 to 6 treatments b. Frequency: 1~~-5~~ to 2 times ~~supervised treatments~~ per week the first 2 weeks~~,~~ as indicated by the severity of the condition. ~~decreasing to 1-3 times~~ Treatment may continue at 1 treatment per week for the next 6 weeks~~, then 1-2 times per week for the next 4 weeks, if necessary~~. c. ~~Optimum~~ Maximum duration: 8 weeks. At week 8, patients should be reevaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at 1 treatment every other week until the

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				patient has reached plateau and maintenance treatments have been determined. Extended durations of care beyond what is considered "maximum" may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Such care should be re-evaluated and documented on a monthly basis. Treatment beyond ~~3~~4-6 visits should be documented with objective improvement in function. Palliative care should be reevaluated and documented at each treatment session. ~~(Colorado, 2003)~~ (Colorado, 2006) Injured workers with complicating factors may need more treatment, if documented by the treating physician. *Number of Visits:* Several studies of manipulation have looked at duration of treatment, and they generally showed measured improvement within the first few weeks or 3-6 visits of chiropractic treatment, although improvement tapered off after the initial sessions. If chiropractic

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				treatment is going to be effective, there should be some outward sign of subjective or objective improvement within the first 6 visits. *Active Treatment versus Passive Modalities:* Manipulation is a passive treatment, but many chiropractors also perform active treatments, and these recommendations are covered under Physical therapy (PT), as well as Education and Exercise. The use of active treatment modalities instead of passive treatments is associated with substantially better clinical outcomes. (Fritz, 2007) Active treatments also allow for fading of treatment frequency along with active self-directed home PT, so that less visits would be required in uncomplicated cases. *Current Research:* A recent comprehensive meta-analysis of all clinical trials of manipulation for low back conditions has concluded that there was good evidence for its use in chronic low back pain, while the evidence for use in radiculopathy was not as

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				strong, but still positive. (Lawrence, 2008) A Delphi consensus study based on this meta-analysis has made some recommendations regarding chiropractic treatment frequency and duration for low back conditions. They recommend an initial trial of 6-12 visits over a 2-4 week period, and, at the midway point as well as at the end of the trial, there should be a formal assessment whether the treatment is continuing to produce satisfactory clinical gains. If the criteria to support continuing chiropractic care (substantive, measurable functional gains with remaining functional deficits) have been achieved, a follow-up course of treatment may be indicated consisting of another 4-12 visits over a 2-4 week period. According to the study, "One of the goals of any treatment plan should be to reduce the frequency of treatments to the point where maximum therapeutic benefit continues to be achieved while encouraging more active self-therapy, such as independent strengthening

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				and range of motion exercises, and rehabilitative exercises. Patients also need to be encouraged to return to usual activity levels despite residual pain, as well as to avoid catastrophizing and overdependence on physicians, including doctors of chiropractic." (Globe, 2008) These recommendations are consistent with the recommendations in ODG, which suggest a trial of 6 visits, and then 12 more visits (for a total of 18) based on the results of the trial, except that the Delphi recommendations in effect incorporate two trials, with a total of up to 12 trial visits with a re-evaluation in the middle, before also continuing up to 12 more visits (for a total of up to 24). Payors may want to consider this option for patients showing continuing improvement, based on documentation at two points during the course of therapy, allowing 24 visits in total, especially if the documentation of improvement has shown that the patient has achieved or maintained RTW.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines 9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Manual therapy & manipulation***	Commenter states that Labor Code §§ 5307.27 and 4604.5 require the guidelines in the Medical Treatment Utilization Schedule to be evidence based and to "address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases." Commenter states that some of the proposed guidelines (for example *Manual therapy & manipulation*) do not appear to be based on the evidence and/or no evidence is referenced.	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Agree in part. Disagree** that the individual treatment guideline topic "Manual therapy & manipulation" does not comply with the requirements of the statute because the guideline "do[es] not appear to be based on the evidence." In the Initial Statement of Reasons, DWC indicated that the 2005 RAND Report identified the Work Loss Data Institute's Official Disability Guidelines (ODG) as meeting the requirements of the statute that the guidelines adopted be "Scientific and Evidence-Based, Peer-Reviewed, and Nationally Recognized." (See, Table 4, p. 21; Table 4.2, p. 27.) RAND used the AGREE Instrument to evaluate the ODG guidelines. (2005 RAND Report, at p. xix.). **Agree** that ODG's references were not included in the DWC version of the individual treatment guideline topic "Manual therapy & manipulation" as included in the chronic pain medical treatment guidelines. ODG has now reviewed the evidence-base, and has updated its individual treatment guideline topic on "manual therapy & manipulation." In its update, ODG expands its reference base. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adopt the updated version in its adapted	See action taken in connection with comment submitted by James E. Lessenger, M.D., dated August 4, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Manual therapy & manipulation, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			version of its chronic pain medical treatment guidelines. The updated version is set forth in connection with the response to the comment submitted by James E. Lessenger, M.D., dated August 4, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Manual therapy & manipulation, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Manual therapy & Manipulation***	Commenter believes that the guidelines should be concise in order to be an effective utilization review reference tool. Commenter also had previously indicated that the red-highlighted language needed attention by the MEEAC. It appears that Commenter recommends striking all language except for the following: "Recommended for chronic pain if caused by musculoskeletal conditions and manipulation is specifically recommended as an option for acute conditions." Regarding topic "Treatment Parameters from state guidelines," commenter opines that this is a very sensitive area and will be controversial. Commenter suggests that the MTUS reference specifically ACOEM for the body part rather than the Colorado guidelines.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Medications for***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Acetaminophen is the initial choice for treatment of acute pain."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
acute pain (analgesics)	"NSAIDs are superior to acetaminophen for some types of pain, and can provide analgesia similar to opioids in some settings, including post-operatively." "Opioids are appropriate for somatic, neuropathic and visceral pain."		Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Medications for acute pain (analgesics)***	Commenter references the ***Medications for acute pain (analgesics)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guidelines as follows: "Recommended as indicated below. Pharmacologic agents are the main treatment of acute pain. Acetaminophen is the initial choice for treatment of acute pain in a dose of 1,000 mg. A recent study found that in a single dose, aspirin was similar to acetaminophen (mg to mg comparison) for treatment of acute pain, although aspirin is more likely to produce GI side effects and hematalogic effects – irreversible inhibitor platelet cyclooxygenase. (Edwards, 2006) (Sachs, 2005) The maximum daily short term dose of acetaminophen is 4,000 mg. There should be caution about daily doses of acetaminophen and liver disease if over 4,000 mg per day or in combination with other NSAIDs. (Watkins, 2006)" "NSAIDs are superior to acetaminophen for some types of pain, and can provide analgesia similar to opioids in some settings, including post-operatively. (Mason, 2006) They ~~suffer from~~ have a ceiling effect above which no additional analgesic effect can be obtained. They also ~~suffer from~~ produce side effects such as GI disturbance, renal dysfunction, increased edema, thrombocytopenia and increased blood pressure. NSAIDs, and the Cox-2 NSAIDS in particular, also are associated with thrombotic cardiovascular events in patients with risk factors."	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** The individual treatment guideline topic for "Medications for acute pain (analgesics)" was removed from the proposed chronic pain medical treatment guidelines after public comments were received objecting to the guideline as a guideline about acute pain, not chronic pain.	The individual topic guideline on "Medications for acute pain (analgesics)" was removed from Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments as the guideline related to acute pain and not chronic pain.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	"Opioids are appropriate analgesics for somatic, neuropathic and visceral pain. Hydrocodone is considered the most potent oral opioid that does not require special documentation for prescribing in some states (not including California). (Quigley, 2006) Prescription ~~S~~side effects include sedation, nausea, vomiting and constipation. There is no evidence that supports the addition of pentazocine (Talwin) or butorphanol (Stadol) to decrease side effects. (Sachs, 2005) This study found a a negative association between receipt of early opioids for acute LBP and outcomes (disability duration, medical costs, subsequent surgery), but severity was also a strong predictor (confounding variable) of all the outcomes and may explain the early opioid use. (Webster, 2007) Tramadol is ~~not~~ additionally recommended as a first-line oral analgesic and is not a controlled substance. ~~because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen~~. There is also no evidence that it has a safer adverse event profile. (Turturro, 1998) Hydrocodone/APAP combinations are subject to a degree of abuse, misuse, and trafficking. Oxymorphine (CII) provides excellent analgesic, no CYP450 drug interactions and a paucity of euphoria (Sloan & Barkin.J OPOPD Management Vol 4, No. 3, May-June 2008."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Medications for subacute & chronic pain***	Commenter references the ***Medications for subacute & chronic pain*** section in the DWC Chronic Pain Treatment Guidelines. Commenter states that the Arthritis Treatment is not properly addressed in the draft (DWC page 41). Commenter indicates that the few places it is addressed, it is handled erroneously (e.g., DWC page 34, Glucosamine). Commenter states that there are now at least two quality RCTs showing delayed progression of destructive joints with this intervention. (Pavelká 02, Reginster 03)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part.** See response to James E. Lessenger, M.D., dated August 4, 2008 above, on Section 9792.24.2(a) Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Glucosamine (and Chondroitin Sulfate) [DWC].	See action taken in connection with comment submitted by James E. Lessenger, M.D., dated August 4, 2008 above, on Section 9792.24.2(a) Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Glucosamine (and Chondroitin Sulfate)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				[DWC].
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Medications for subacute & chronic pain***	Commenter states that the ***Medications for subacute & chronic pain*** section in the DWC Chronic Pain Treatment Guidelines states (page 41, first sentence) that "there are few studies of the use of medications in the sub acute … or chronic pain periods." Commenter states that there are over 50 RCTs in this area that should be the foundation for quality evidence-based guidelines for injured workers in California. Commenter states that the ***Medications for subacute & chronic pain*** section in the DWC Chronic Pain Treatment Guidelines (page 41) links generalized recommendations for osteoarthritis medications to chronic pain conditions, and refers to a section. Commenter also states that "There are multiple medication choices in the *Procedure summary"* that do not exist within the document. Commenter adds that the paragraph also lists medication choices implying recommendation for chronic pain, several of which are explicitly not recommended elsewhere in the document. Commenter makes reference to Appendix 2 attached to the comments submitted. Commenter submits Appendix 2 to his August 7, 2008 correspondence. Appendix 2 lists what commenter identifies as contradictory Medication Choices (commenter references the chronic pain guidelines at pp. 41-42): Anticonvulsants for chronic pain; Antidepressants for chronic pain; Antidepressants for neuropathic pain; Antidepressants for non-neuropathic pain; Anti-Inflammatories; Benzodiazepines; Not Recommended (p. 19); Boswellia Serrata Resin (Frankincense); Not Recommended (p. 20); Cannabinoids; Not Recommended (p. 21);	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part.** Commenter is correct that the evidence-base is substantial as opposed to as indicated in the individual treatment guideline topic of "Medications for subacute & chronic pain." ODG has now reviewed the evidence-base, and has updated its individual treatment guideline topic on "medications for subacute & chronic pain." In its update, ODG expands its reference base. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment guidelines. The updated version is set forth in the action column of this chart for the benefit of the regulated public. Moreover, the title of the guideline was modified by removing the reference to subacute pain. DWC received public comments objecting to the references in the proposed chronic pain medical treatment guidelines to "acute" and "subacute" pain" on the grounds that the guidelines should only be applicable to chronic pain. DWC **agrees**. The title of the individual topic treatment guideline for "medications for subacute & chronic pain" has been modified to read: "medications for chronic	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Medications for subacute & chronic pain***, has been revised as follows: **"Medications for ~~subacute &~~ chronic pain** "Recommended as indicated below. ~~There are few studies of the use of medications in the subacute period (7 to 12 weeks) or chronic period of pain treatment.~~ Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Capsaicin; Cod liver oil; Not Recommended (p. 25); Curcumin (Turmeric); Not Recommended (p. 32); Cyclobenzaprine (Flexeril®); Duloxetine (Cymbalta®); Gabapentin (Neurontin®); Glucosamine (and Chondroitin Sulfate); Not Recommended (p. 34); Green tea; Not Recommended (p. 34); Herbal medicines; Implantable drug-delivery systems (IDDSs); Injection with anaesthetics and/or steroids; Intrathecal drug delivery systems, medications; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Not Recommended (p. 49); Ketamine; Not Recommended (p. 50); Methadone; Milnacipran (Ixel®); Not Recommended (p. 43); Muscle relaxants; Nonprescription medications; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; Opioids (with links to multiple topics on opioids); Pycnogenol (maritime pine bark); Not Recommended (p. 86); Salicylate topicals; Topical analgesics; Uncaria Tomentosa (Cat's Claw); Not Recommended (p. 80); Venlafaxine (Effexor®); White willow bark; Not Recommended (p. 81); Ziconotide (Prialt®)		pain." Commenter also states that "[t]here are multiple medication choices in the *Procedure summary"* that do not exist within the document. The chronic pain medical treatment guidelines do not contain a "procedure summary" section. Thus, ODG corrected this by deleting the reference to the "procedure summary" section. Commenter argues that the guideline lists medication choices implying recommendation for chronic pain, several of which are explicitly not recommended elsewhere in the document. Commenter submits and references Appendix 2, which commenter attached to the comments submitted. ODG clarified its guideline by stating that the list of drugs referenced by commenter and as listed in the guideline are "not all recommended." The specific language is as follows: "There are multiple medication choices listed separately (not all recommended)."	that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices ~~in the Procedure Summary~~ listed separately (not all recommended). See **Anticonvulsants for chronic pain; Antidepressants for chronic pain**; ~~Antidepressants for neuropathic pain; Antidepressants for non-neuropathic pain;~~ **Anti-**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				epilepsy drugs (AEDs); **Anti-Inflammatories**; **Benzodiazepines**; **Boswellia Serrata Resin (Frankincense)**; **Buprenorphine**; **Cannabinoids**; **Capsaicin**; **Cod liver oil**; **Curcumin (Turmeric)**; **Cyclobenzaprine (Flexeril®)**; **Duloxetine (Cymbalta®)**; **Gabapentin (Neurontin®)**; **Glucosamine (and Chondroitin Sulfate)**; **Green tea**; **Herbal medicines**; **Implantable drug-delivery systems (IDDSs)**; **Injection with anaesthetics and/or steroids**; **Intrathecal drug delivery systems, medications**; **Intravenous regional sympathetic blocks (for RSD, nerve blocks)**; **Ketamine**; **Methadone**; **Milnacipran (Ixel®)**; **Muscle relaxants**; **Nonprescription medications**; **NSAIDs (non-steroidal anti-inflammatory drugs)**; **NSAIDs, GI symptoms & cardiovascular risk**; **Opioids (with links to multiple topics on opioids)**; **Pycnogenol (maritime pine bark)**; **Salicylate topicals**;

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Topical analgesics; **Topical analgesics, Compounded**; **Uncaria Tomentosa (Cat's Claw)**; **Venlafaxine (Effexor®)**; **White willow bark**; & **Ziconotide (Prialt®)**."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Medications for subacute & chronic pain***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Subacute period (7 to 12 weeks). Only one medication should be given at a time."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Medications for subacute & chronic pain***	Commenter references the ***Medications for subacute & chronic pain*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "There are few studies of the use of medications in the subacute period (7 to 12 weeks) or chronic period of pain treatment. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the ~~aim of use~~ focused outcome of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference; (4) determine the patient's CLCR for dose/interaction selection; (5) the CYP 450 drug interaction. Only one medication should be given at a time, and interventions that are active and	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Disagree** with commenter's suggestion to remove the brand name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability. Moreover, DWC **disagrees** with commenter's suggested edits as they do not substantively improve the guideline language. Nevertheless, through ODG's internal evidence evaluation review process, ODG has updated its individual topic guideline on "medications for subacute & chronic pain." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment	See action taken in connection with comment received by ACOEM, Barry Eisenberg, Executive Director, August 7, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Medications for subacute & chronic pain***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	passive should remain unchanged at the time of the medication change. A therapeutic trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices in the Procedure Summary. See Anticonvulsants for chronic pain; Antidepressants for chronic pain; Antidepressants for neuropathic pain; Antidepressants for non-neuropathic pain; Anti-Inflammatories; Benzodiazepines; Boswellia Serrata Resin (Frankincense); Cannabinoids; Capsaicin; Cod liver oil; Curcumin (Turmeric); Cyclobenzaprine ~~(Flexeril®)~~; Duloxetine ~~(Cymbalta®)~~; Gabapentin ~~(Neurontin®)~~; Glucosamine (and Chondroitin Sulfate); Green tea; Herbal medicines; Implantable drug-delivery systems (IDDSs); Injection with anaesthetics and/or steroids; Intrathecal drug delivery systems, medications; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Ketamine; Methadone; Milnacipran (Ixel®)[Not yet available in the USA]; Muscle relaxants; Nonprescription medications; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; Opioids (with links to multiple topics on opioids); Pycnogenol (maritime pine bark); Salicylate topicals; Topical analgesics; Uncaria Tomentosa (Cat's Claw); Venlafaxine ~~(Effexor®)~~; White willow bark; & Ziconotide (Prialt®)."		guidelines. It is noted that the title of the individual topic treatment guideline for "medications for subacute & chronic pain" has been modified to read: "medications for chronic pain." DWC received public comments objecting to the references in the proposed chronic pain medical treatment guidelines to "acute" and "subacute" pain" on the grounds that the guidelines should only be applicable to chronic pain. DWC **agrees** with these comments, and the revised individual topic guideline for the reasons set forth in the response to the comment submitted by ACOEM, Barry Eisenberg, Executive Director, August 7, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Medications for subacute & chronic pain, above.	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Methadone***	Commenter states that ***Methadone*** is a dangerous drug. Commenter opines that the section on this topic appears to mute the dangers. Commenter indicates that it is highly questionable whether this is an appropriate intervention in employed individuals. Commenter observes that there is no discussion in this section or in the document about safety sensitive positions, suggesting a lack of sensitivity towards the potential for an impaired individual to injure a co-worker. Commenter adds that there is also the risk to the public when a methadone treated injured worker operates a motor vehicle. (Page 42.)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree.** ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "Methadone." ODG's updated individual treatment guideline topic of Methadone emphasizes the risks involved using this drug. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain, Intervention and Treatments, ***Methadone***, has been revised as follows: **"Methadone** "Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it. (Clinical Pharmacology, 2008) *Pharmcokinetics:* Genetic differences appear to influence how an individual will respond to this medication. Following oral administration, significantly different blood concentrations may be obtained. Vigilance is suggested in treatment initiation, conversion from

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				another opioid to methadone, and when titrating the methadone dose. (Weschules 2008) (Fredheim 2008) *Adverse effects:* Delayed adverse effects may occur due to methadone accumulation during chronic administration. Systemic toxicity is more likely to occur in patients previously exposed to high doses of opioids. This may be related to tolerance that develops related to the N-methyl-D-aspartate (NMDA) receptor antagonist. Patients may respond to lower doses of methadone than would be expected based on this antagonism. One severe side effect is respiratory depression (which persists longer than the analgesic effect). Methadone should be given with caution to patients with decreased respiratory reserve (asthma, COPD, sleep apnea, severe obesity). QT prolongation with resultant serious arrhythmia has also been noted. Use methadone carefully in patients with cardiac hypertrophy and in patients at risk for hypokalemia (including those patients on diuretics).

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Methadone does have the potential for abuse. Precautions are necessary as well for employees in safety sensitive positions, including operation of a motor vehicle. **Steps for prescribing methadone:** (1) *Basic rules* - Weigh the risks and benefits before prescribing methadone. - Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction. - Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments. (2) *Know the information that is vital to give the patient:* - Don't be tempted to take more methadone than prescribed if you are not getting pain relief. This can lead to a dangerous build-up that can cause death. - All changes in methadone dose should be made by your treating practitioner. - Methadone can make your breath slow down, or

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				actually stop. - Methadone can slow down your heartbeat and you might not be able to detect this. - If you feel like you are having an irregular heartbeat, dizziness, light-headedness or fainting, call your doctor or clinic immediately. (FDA, 2006) (3) *Be familiar with the current SAMHSA health advisory on methadone* - The medication has become more accessible to unauthorized users. - It can accumulate in potentially harmful doses (especially during the first few days of treatment). -There has been a rise in Methadone-associated mortality. (SAMHSA, 2004) (4) *Be familiar with the FDA final policy statement on Methadone that explicitly discusses the topic, "Can Methadone be used for pain control?"* No separate registration is required to prescribe methadone for treatment of pain. (DEA, 2006) (5) *Read the new prescribing information for Methadone and the new patient information section.* (Roxane, 2006)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				(6) Multiple potential drug-drug interactions can occur with the use of Methadone. A complete list of medications should be obtained prior to prescribing methadone to avoid adverse events, and the patient should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Methadone***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Recommended for moderate to severe pain. Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Methadone***	Commenter references the ***Methadone*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended for moderate to severe pain with cautious use, careful monitoring. The FDA reports that they have received reports of severe morbidity and mortality with this medication even at low doses. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Vigilance is suggested in	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** Commenter's concerns are warranted. **Agree** for the reasons set forth in the response to comment submitted by ACOEM, Barry Eisenberg, Executive Director, dated August 7, 2008, on 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Methadone, above. **Disagree** with commenter's suggested edits as they do not substantively improve	See action taken in connection with comment submitted by ACOEM, Barry Eisenberg, Executive Director, dated August 7, 2008, on 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Methadone***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	treatment initiation, conversion from another opioid to methadone, and when titrating the methadone dose. One severe side effect is respiratory depression (which persists longer than the analgesic effect). Methadone should be given with caution to patients with decreased respiratory reserve (asthma, COPD, sleep apnea, severe obesity). QT prolongation with resultant serious arrhythmia has also been noted at low doses. Use methadone carefully in patients with cardiac hypertrophy and in patients at risk for hypokalemia (including those patients on diuretics). Methadone does have the potential for abuse." "Steps for prescribing methadone: (1) Basic rules • Weigh the risks and benefits before prescribing methadone. • Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction. • Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments. • Obtain baseline EKG and order periodically especially before and following dose changes. (2) Know the information that is vital to give the patient: • Don't be tempted to take more methadone than prescribed if you are not getting pain relief. This can lead to a dangerous build-up		the guideline language.	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	that can cause death. • All changes in methadone dose should be made by ~~your treating~~ one practitioner." Commenter further references the "methadone" treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "(5) Read the new prescribing information for Methadone and the new patient information section. (Roxane, 2006) "(6) See **Methadone**: **unintended mortality due** to **overdose** and arrhythmia FW Burgess, MJ Krantz, RL Barkin - Pain Medicine, 12/2007"			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines ***Part 2. Pain Intervention and Treatments Milnacipran (Ixel®) [DWC]***	Commenter states that the treatment guideline for **Milnacipran (Ixel®)** is listed under medications for Acute and Chronic Pain page 41), but yet under its description it is designated as not recommended, not approved by the FDA and not available in the US. Currently under an NDA, the DWC should be wary about predicting the outcome of a FDA drug evaluation for marketing in the US determination and also de novo including such a recommendation without any evidence of efficacy in injured workers comp chronic pain. (Page 43, par 3.)	Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** Commenter appears to state that DWC cannot predict a Federal Drugs Administration's (FDA) outcome with respect to the individual topic guideline on "Milnacipran (Ixel®)." The purpose of the MTUS is to provide guidelines that are applicable at present time, not what may happen in the future. Rather, until the FDA approves the use of "Milnacipran (Ixel®)," the MTUS is presumptively correct as to the use of this drug. If and when the FDA approves any new drug or new indication for a drug, then when that occurs, DWC will proceed to conduct a new rulemaking to revise the MTUS, and specifically the chronic pain medical treatment	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, ***Part 2, Pain Intervention and Treatments***, ***Milnacipran (Ixel®) [DWC]***, has been modified as follows: **"Milnacipran (Ixel®) ~~[DWC]~~** "Not Recommended as ~~-~~ It is not FDA approved and not available in the US at this time. Under study as a treatment for fibromyalgia syndrome. An FDA Phase III study demonstrated "significant therapeutic effects" of milnacipran for

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			guidelines. Nevertheless, through ODG's internal evidence evaluation review process, ODG has updated its individual topic guideline on "Milnacipran (Ixel®)." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment guidelines. The revised guideline is set forth in the action column for the benefit of the regulated public.	treatment of fibromyalgia syndrome. Milnacipran (San Diego's Cypress Bioscience Inc.) has been approved for the treatment of depression outside of the U.S. and is in a new class of antidepressants known as Norepinephrine Serotonin Reuptake Inhibitors (or NSRIs). What makes Milnacipran different from the Selective Serotonin Reuptake Inhibitors (SSRIs) – drugs like Prozac® – and Selective Norepinephrine Reuptake Inhibitors (SNRIs) – drugs like Effexor® – is that Milnacipran affects two neurotransmitters, norepinephrine and serotonin. (Rooks, 2007)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Milnacipran (Ixel®) [DWC]**	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Muscle relaxants***. Commenter quotes a portion of the guideline as follows: "Recommended non-sedating muscle relaxants with caution as a second-line option for acute LBP [lower back pain] and for short-term pain relief in patients with chronic LBP, but	James E. Lessenger, M.D. August 4, 2008	**Agree in part.** DWC **disagrees** with the comment as it is non-responsive and does not address the substance of the individual topic guideline on "muscle relaxants." Moreover, **disagree** with commenter's comparison of	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Muscle relaxants***, has been modified as follows:

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Muscle relaxants	benzodiazepines are not recommended." Commenter questions the use of the words "with caution." Commenter wants to know what it means in the context of the guideline. He questions whether it means that everybody uses or is supposed to use caution. He opines that this is a meaningless recommendation and will be of no use in utilization review or as a reference. Commenter adds that the ACOEM Chronic Pain Update recommends ***Muscle relaxants***. Commenter observes that the recommendation uses is 3 pages long, contains 4 recommendations, references 9 RCTs, 3 systemic reviews, 1 guideline, 2 low quality RCTs.		ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "muscle relaxants." Commenter's intention is not clear as his comments in this regard do not address the substance of the regulations, and offer no substantive suggestion to improve the guideline. Nevertheless, through ODG's internal evidence evaluation review process, ODG has updated its individual topic guideline on "muscle relaxants." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment guidelines.	**"Muscle relaxants (for pain)** "Recommend non-sedating muscle relaxants with caution as a second-line option for~~ acute LBP and for~~ short-term ~~pain relief~~ treatment of acute exacerbations in patients with chronic LBP~~, but benzodiazepines are not recommended~~. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) ~~Muscle relaxants are a broad range of medications that are generally divided into antispasmodic and antispasticity drugs. (van Tulder, 2006) Antispasmodics are used to decrease muscle spasm in conditions such as LBP. These can be benzodiazepines (See Benzodiazepines) and non-benzodiazepines. Antispasticity drugs are used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries. These latter drugs block the sarcoplasmic reticulum calcium channel.~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. ~~Metaxalone (Skelaxin®) is reported to be a relatively non-sedating muscle relaxant. Carisoprodol (Soma®) is metabolized to meprobamate, an anxiolytic. There is a school of thought that its main effect is due to generalized sedation. Withdrawal symptoms may occur with abrupt discontinuation. (Reeves, 2003) See Weaning of medications. Soma has been noted to be a street drug of~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~abuse and is often combined with acetaminophen and codeine, a combination labeled as "Soma-Coma". (Schears, 2004) Cyclobenzaprine (Flexeril®) has similar effects to tricyclic antidepressants. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. See Cyclobenzaprine. Muscle relaxants are effective in acute LBP. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement and is associated with drowsiness and dizziness. Carisoprodol is also effective but has abuse and dependency potential. Metaxalone and low dose cyclobenzaprine have fewer adverse effects. (Kinkade, 2007)~~ Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in *American Family Physician*, skeletal muscle relaxants are the most widely

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008) *Classifications:* Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. (See, 2008) (van Tulder, 2006)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Muscle relaxants***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommend non-sedating muscle relaxants with caution as a second-line option for acute LBP and for short-term pain relief in patients with chronic LBP, but benzodiazepines are not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and	Commenter references the ***Muscle relaxants*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows:	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggestion to remove the brand name of the drug. DWC agrees with ODG's practice that while major listings use generic names, ODG also includes brand names	See action taken in connection with comments submitted by James E. Lessenger, M.D., dated August 4, 2008, on Section 9792.24.2(a), Chronic Pain

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments ***Muscle relaxants***	**"Muscle relaxants (do not work at myoneural junction, aside dantrolene)** Recommend non-sedating muscle relaxants with caution as a second-line option for acute LBP and for short-term pain relief in patients with chronic LBP, but benzodiazepines are not recommended. (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2006) (Schnitzer, 2004) Muscle relaxants are a broad range of medications that are generally divided into antispasmodic and antispasticity drugs. (van Tulder, 2006) Antispasmodics are used to decrease muscle spasm in conditions such as LBP. These can be benzodiazepines (See Benzodiazepines) and non-benzodiazepines. Antispasticity drugs are used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries. These latter drugs block the sarcoplasmic reticulum calcium channel. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Metaxalone (Skelaxin®) is reported to be a relatively non-sedating muscle relaxant. Carisoprodol ~~(Soma®)~~ is metabolized to meprobamate, an anxiolytic. There is a school of thought that its main effect is due to generalized sedation. Withdrawal symptoms may occur with abrupt discontinuation. (Reeves, 2003) See Weaning of medications. ~~Soma~~ It has been noted to be a street		for usability. Moreover, **disagree** with commenter's suggested edits as they do not substantively improve the guideline language. For example, Commenter's suggesting that the following "(do not work at myoneural junction, aside dantrolene)" be inserted after parenthetical the title "Muscle relaxants," is addressed by ODG in its own language as follows: "**Dantrolene (Dantrium®, generic available):** Not recommended. The mechanism of action is a direct inhibition of muscle contraction by decreasing the release of calcium from the sarcoplasmic reticulum. (At p. 66.) Moreover, other suggestions by commenter are unnecessary because ODG has re-written entire portions of its guideline to which commenter makes edits. Those sections are no longer part of the guideline. As previously indicated, through ODG's internal evidence evaluation review process, ODG has updated its individual topic guideline on "muscle relaxants." See response in connection with comments submitted by James E. Lessenger, M.D., dated August 4, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments,	Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Muscle relaxants***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	drug of abuse and is often combined with acetaminophen and codeine, a combination labeled as "Soma-Coma." (Schears, 2004) Cyclobenzaprine ~~(Flexeril®)~~ has similar effects to tricyclic antidepressants. It is a controlled substance in various states. It is used with cocaine abusers to decrease the post dose cocaine "crash." It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. See Cyclobenzaprine. Muscle relaxants are effective in acute LBP. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement and is associated with multiple receptor non-therapeutic effects which include drowsiness and dizziness. Carisoprodol is also effective but has prominent abuse and dependency potential. Metaxalone and low-dose cyclobenzaprine have fewer adverse effects. (Kinkade, 2007)\ A complete review of clinical and pharmacologic review of skeletal muscle relaxants for musculoskeletal conditions is available (AMJ Ther 2005 Mar-April, 12(7) 151-71 REVIEW (Beeke, Barkin)."		Muscle relaxants, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Neurontin®***	Commenter references the ***Neurontin®*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "**Neurontin® (Generic)** See Gabapentin"	Robert L. Barkin, PharmD, M.B.A.	**Agree in Part. Agree** with commenter clarifying the reference in the individual treatment guideline topic of "Neurontin®." ODG has updated the individual treatment guideline topic of "Neurontin®" to clarify the brand name of the drug and the generic name of the drug. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. DWC **disagrees** with the specific edit of the commenter,	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Neurontin®,*** has been revised as follows: **"Neurontin® (gabapentin)** "Neurontin® is a brand name for gabapentin produced by Pfizer subsidiary Parke-Davis. See Gabapentin.**"**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			as the correct name of the generic drug is more appropriate.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Nonprescription medications***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended." Commenter suggests that this may be a good place for the MTUS to address the "non-medical treatment" drugs for food drugs and comment about the regulations to cover these items. Commenter stresses that this is an area of great controversy with clients and this is felt to be non-medical and therefore not consistent with the provision for "medical treatment" in the Labor Code.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part. Disagree** with the recommendation to edit the guideline for the reasons set forth in the response to comment submitted by Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. **Agree** that the chronic pain medical treatment guidelines should address the "medical foods" issue. It is noted that the 45-day chronic pain medical treatment version did not contain any individual medical treatment topic on medical foods. DWC proposes to adapt ODG's updated version dated October 23, 2008 in the chronic pain medical treatment guidelines. Upon review of ODG's October 23, 2008 updated version, DWC has determined that it contains individual treatment guideline topics or relevant portions of a individual treatment guideline topics which contain treatment recommendation for medical foods. These references were not included in the ODG October 23, 2008 version, as adapted by DWC, because they do not relate to chronic pain. This action is	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			specified in the MTUS, 1st 15 Day Notice, Appendix A1, November 2008, pp. 15-16, in relevant part, as follows: **"4. Deletion of an ODG individual treatment topic or relevant portions of a topic when the treatment recommendation does not relate to chronic pain.** The individual treatment topics, or relevant portions of a topic, when the treatment recommendations do not relate to chronic pain were omitted from the chronic pain medical treatment guidelines as the text in the guidelines was not directly related to chronic pain. … Further, with regard to reviewing individual medical foods, ODG did not specify how these medical foods are used for chronic pain conditions. Without such specification, these medical foods are deleted. *** (10) Medical Foods (a) Choline (b) Glutamic Acid (c) Gamma-aminobutyric acid (GABA) (d) L-Serine (e) L-Arginine	
9792.24.2(a) Chronic Pain Medical Treatment	Commenter references the ***Nonprescription medications*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits are inconsistent with ODG's style and do not substantively	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines Part 2. Pain Intervention and Treatments ***Nonprescription medications***	Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended. Acetaminophen (safest); NSAIDs (aspirin, ibuprofen, naproxen, ketoprofen). (Bigos, 1999) There should be caution about daily doses of acetaminophen and liver disease if over 4 g/day or in combination with other NSAIDs. Use of 2000-2300 mg/d may be a better choice for chronic use in selected patients. (Watkins, 2006) See also NSAIDs (non-steroidal anti-inflammatory drugs)."		improve the guideline language.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Norepinephrine serotonin reuptake inhibitors (NSRIs)***	Commenter references the ***Norepinephrine serotonin reuptake inhibitors (NSRIs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: **"Seratonin Norepinephrine ~~serotonin~~ reuptake inhibitors ~~(NSRIs)~~ (SNRI)** See Duloxetine (Cymbalta®); & Milnacipran (Ixel®)"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** Commenter's suggested edits are inconsistent with ODG's style and do not substantively improve the guideline language.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***NSAIDs (non-steroidal anti-inflammatory drugs)***	Commenter states that the ***NSAIDs*** section persists in the belief that acetaminophen (or the analog paracetamol) may be as effective as NSAIDs for acute LBP. Commenter states that as yet quality evidence suggests inferiority to Diflunisal, mefenamic acid, indomethacin, and aspirin. (Hickey 82; Evans 80).(Page 44, par 9)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part. Agree** with commenter for the reasons set forth in the response to comment submitted by Robert L. Barkin, PharmD, M.B.A., on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Acetaminophen, above. **Disagree** with commenter's references as ODG's evidence is more recent than those cited by commenter.	See action taken in connection with comment submitted by Robert L. Barkin, PharmD, M.B.A., on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Acetaminophen***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter states the NSAIDs are nephrotoxic. Commenter states that there should be a strong warning that NSAIDs should not be used in the face of renal impairment.	Philipp M. Lippe, M.D. Medical Corporation, Consultant	**Agree.** ODG has conducted its own evidence-based review and has updated the individual treatment guideline topic of	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments ***NSAIDs (non-steroidal anti-inflammatory drugs)***		August 11, 2008	"NSAIDs (non-steroidal anti-inflammatory drugs)." The revised guideline now contains a section entitled: "NSAIDs, hypertension and renal function," which warns about nephrotoxicity (renal impairment). DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. The revised guideline is set forth in the action column for the benefit of the regulated public.	Treatments, ***NSAIDs (non-steroidal anti-inflammatory drugs)*** has been revised as follows: **"NSAIDs (non-steroidal anti-inflammatory drugs)** "~~Recommended for acute pain, acute LBP, short-term pain relief in chronic LBP, and short-term improvement of function in chronic LBP.~~ "Specific recommendations: *Osteoarthritis (including knee and hip):* Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) *Back Pain - Acute exacerbations of chronic pain:* Recommended as a second-line treatment after acetaminophen. In general, ~~T~~there is conflicting evidence that NSAIDs are more effective that acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) *Back Pain - Chronic low back pain:* Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. *Neuropathic pain:* There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in ~~this condition~~ with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; ~~and Medications for acute pain (analgesics).~~ Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) **"NSAIDs, GI symptoms & cardiovascular risk** "Recommend with

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				precautions as indicated below. *Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors.* *Determine if the patient is at risk for gastrointestinal events:* (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that *H. Pylori* does not act synergistically with NSAIDS to develop gastroduodenal lesions. "Recommendations *Patients with no risk factor and no cardiovascular disease*: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) "*Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:*(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 µg four times daily) or (2) a Cox-2 selective agent. Long-term

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). "*Patients at high risk for gastrointestinal events with no cardiovascular disease*: A Cox-2 selective agent plus a PPI if absolutely necessary. *Patients at high risk of gastrointestinal events with cardiovascular disease:* If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) "*Cardiovascular disease:* A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. "*Major risk factors (recent MI, or coronary artery surgery, including recent stent placement)*: If NSAID

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. *Mild to moderate risk factors:* If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. ~~Progressive medications include introducing an NSAID with Cox-2 activity~~. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) *Use with Aspirin for cardioprotective effect:* *In terms of GI protective effect:* The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors.. (Laine, 2007) ~~Ibuprofen appears to attenuate the antiplatlet effect of enteric-~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~coated aspirin and should be taken 30 minutes after ASA or 8 hours before. (Antman, 2007)~~ *In terms of the actual cardioprotective effect of aspirin*: Traditional NSAIDs (both ibuprofen and naproxen) appear to attenuate the antiplatlet effect of enteric-coated aspirin and should be taken 30 minutes after ASA or 8 hours before. (Antman, 2007) Cox-2 NSAIDs and diclofenac (a traditional NSAID) do not decrease anti-platelet effect. (Laine, 2007) *Use of NSAIDs and SSRIs:* The concurrent use of SSRIs and NSAIDs is associated with moderate excess relative risk of serious upper GI events when compared to NSAIDs alone. This risk was higher for non-selective NSAIDs when compared to Cox-2 selective agents (adjusted odds ratio of 1.77 and 1.33, respectively). (Helin-Salmivaara, 2007) *Treatment of dyspepsia secondary to NSAID therapy:* Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				"NSAIDs, hypertension and renal function "Recommend with precautions as indicated below. NSAIDs can increase blood pressure by an average of 5 to 6 mm in patients with hypertension. They may cause fluid retention, edema, and rarely, congestive heart failure. (Sustained blood pressure elevation in the elderly is associated with increases in hemorrhagic stroke, congestive heart failure and ischemic cardiac events.) The risk appears to be higher in patients with congestive heart failure, kidney disease or liver disease. *Normotensive patients:* NSAIDs appear to have minimal effect on blood pressure in normotensive patients. (Laine, 2007) *Hypertensive patients:* All NSAIDs have the potential to raise blood pressure in susceptible patients. The greatest risk appears to occur in patients taking the following anti-hypertensive therapy: angiotensin-converting enzyme (ACE)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				inhibitors; angiotensin receptor blockers; beta-blockers; or diuretics. In addition congestive heart failure may develop due to fluid retention. *Patients with mild to moderate renal dysfunction:* All NSAIDs are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess (such as cirrhosis). Oral opioids are an option for treatment. *Treatment recommendations:* Blood pressure should be measured as well as evidence of fluid excess in normotensive patients within 2-4 weeks of beginning treatment and on each visit. **"NSAIDs, specific drug list & adverse effects** "Recommended with cautions below. Disease-State Warnings for all NSAIDs: All NSAIDS have **[U.S. Boxed Warning]**: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDS should never be

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. *Other disease-related concerns (non-boxed warnings): Hepatic:* Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. *Renal:* Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. *Routine Suggested Monitoring*: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. *Overall Dosing Recommendation*: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. Specific NSAID Classes are outlined below: "***Selective COX-2 NSAIDS:*** Celecoxib (Celebrex®) is the only available COX-2 in the United States. No generic is available. *Mechanism of Action:* Inhibits prostaglandin synthesis by decreasing cyclooxygenase-2 (COX-2). At therapeutic concentrations, cyclooxygenase-1 (COX-1) is not inhibited. In animal models it works as an anti-inflammatory, analgesic, and antipyretic. It does not have an anti-platelet effect and is not a substitute for aspirin for cardiac prophylaxis. *Use:* Relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, [and]

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				ankylosing spondylitis. *Side Effects:* See NSAIDs, hypertension and renal function; & NSAIDs, GI Symptoms and Cardiovascular Risks. *Cardiovascular*: Hypertension (<13%) *CNS*: headache (15.8%), dizziness (1% - 2%), insomnia (2.3%); *GI*: diarrhea (4% to 11%), dyspepsia (8.8% vs. 12.8% for ibuprofen and 6.2% for placebo), diarrhea (5.6%), abdominal pain (4.1% vs. 9% for ibuprofen and 2.8% for placebo), N/V (3.5%), gastroesophogeal reflux (≤ 5%), flatulence (2.2%); *Neuromuscular/ skeletal*: arthralgia (7%), back pain (3%); *Respiratory*: upper respiratory tract infection (8%), cough (7%), sinusitis (5%), rhinitis (2%), pharyngitis (2%); *Skin Rash* (2%) – discontinue if rash develops; *Peripheral Edema* (2.1%). *Recommended Dose:* 200 mg a day (single dose or 100 mg twice a day). (Celebrex® package insert) "***Combination (NSAID/GI protectant)*:** Arthrotec® (diclofenac/ misoprostol) 50mg/200mcg, 75mg/20mcg. **[Black Box**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Warning]: Do not administer Arthrotec®/misoprostol to pregnant women because it can cause abortion. *Mechanism of action:* Combines a diclofenac (an NSAID) with misoprostol, an agent that inhibits basal and nocturnal gastric acid secretion and has some mucosal protective properties. Misoprostol is available as Cytotec®. *Uses:* Indicated for the treatment of the signs and symptoms of osteoarthritis in patients at high risk for developing NSAID-induced gastric or duodenal ulcers and their complications. These two products are available as separate medications if you need to individualize therapy. *Side Effects:* See diclofenac. *Misoprostol side effects: (*vs. diclofenac alone). The following symptoms were increased over and above that found for diclofenac alone with the addition of misoprostol: Abdominal pain (21% with Arthrotec and 15% with diclofenac); Diarrhea (19% with Arthrotec vs. 11% with diclofenac); Dyspepsia (14% for Arthrotec vs. 11% for

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				diclofenac); Nausea/vomiting (11% for Arthrotec vs. 6% for diclofenac); Flatulence (9% for Arthrotec vs. 4% for diclofenac). Diarrhea and abdominal pain usually resolve in 2 to 7 days. *Dosing:* The recommended dose for OA is diclofenac 50mg/misoprostol 200mcg t.i.d. In patients that may not tolerate this dose, 50mg/200mcg b.i.d and 75mg/200mcg b.i.d. may be prescribed, but are somewhat less effective in ulcer prevention. (Arthrotec® Package Insert) (Bocanegra, 1998) ***NONSELECTIVE NSAIDS*:** (Inhibits COX-1 and COX-2) Mechanism of action: Inhibits prostaglandin synthesis by decreasing the activity of the enzymes COX-1 and COX-2, which results in decreased formation of prostaglandins involved in the physiologic response of pain and inflammation. Side Effects: See Disease-state warnings above. Other common side effects include the following. CNS: headache, dizziness, insomnia; Skin: rash including life-threatening

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				skin reactions (Stevens-Johnson syndrome) **Discontinue if rash develops**; GI: abdominal cramps, nausea/vomiting, diarrhea, constipation, flatulence; Otic: Tinnitus; Hematologic: Anemia. Specific NSAIDS are listed below: "*Diclofenac Sodium (Voltaren®, Voltaren-XR®) generic available:* (Voltaren®, diclofenac sodium enteric-coated tablet Package Insert), (Voltaren®-XR, diclofenac sodium extended-release tablets Package Insert) *Diclofenac Potassium (Cataflam®, generic available):* (Cataflam®, diclofenac potassium immediate-release tablets Package Insert) Different formulations of diclofenac are not necessarily bioequivalent. *Dosing:* Cataflam®: *Osteoarthritis: Adults:* 50 mg PO 2—3 times daily. Dosages > 150 mg/day PO are not recommended. *Pain*: 50mg PO 3 times per day (max dose is 150mg/day). An initial dose of 100 mg PO followed by 50-mg doses

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				may provide better relief. Voltaren®: *Osteoarthritis:* 50 mg PO 2—3 times daily or 75 mg PO twice daily. Dosages > 150 mg/day PO are not recommended. *Ankylosing spondylitis*: 25 mg PO 4 times a day with an extra 25-mg dose at bedtime if necessary. Voltaren®-XR: 100 mg PO once daily for chronic therapy. Voltaren®-XR should only be used as chronic maintenance therapy. *Diflunisal(Dolobid®, generic available): Dosing: Mild to moderate pain* (arthralgia, bone pain, myalgia); 1 gm initially, followed by 500mg every 12 hours; some patients may require 500mg PO every 8 hours (Max 1500mg/day). *Osteoarthritis*: 250-500mg PO twice daily (Max 1500mg/day). (Dolubid® Package Insert) *Etodolac(Lodine®, Lodine XL®, generic available): Dosing:* Lodine®: *Osteoarthritis*: 300mg PO 2-3 times daily or 400 – 500mg twice daily (doses > 1000mg/day have not been evaluated). Lodine®-XL: *Osteoarthritis:* 400 to 1000 mg once daily. A therapeutic response may not be seen for

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				1-2 weeks. *Fenoprofen (Nalfon®, generic available):* 200, 600 mg. *Dosing: osteoarthritis;* (off-label use for ankylosing spondylitis); 300 – 600mg PO 3 to 4 times per day (Max daily dose is 3200mg). Improvement may take as long as 2 to 3 weeks. *Mild to moderate pain* (off-label use for bone pain): 200mg PO every 4 to 6 hours as needed. *Flurbiprofen (Ansaid®, generic available):* 50, 100 mg. *Dosing: Osteoarthritis and mild to moderate pain:* 200-300mg per day at intervals of 2 to 4 divided doses. The maximum daily dose is 300 mg/day and the maximum divided dose is 100 mg (for instance, 100 mg twice a day). *Ibuprofen (Motrin®, Advil® [otc], generic available):* 300, 400, 600, 800 mg. *Dosing: Osteoarthritis and off-label for ankylosing spondylitis:* 1200 mg to 3200 mg daily. Individual patients may show no better response to 3200 mg as 2400 mg, and sufficient clinical improvement should be observed to offset potential risk of treatment with the increased dose. Higher doses

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				are generally recommended for rheumatoid arthritis: 400-800 mg PO 3-4 times a day, use the lowest effective dose. Higher doses are usually necessary for osteoarthritis. Doses should not exceed 3200 mg/day. *Mild pain to moderate pain*: 400 mg PO every 4-6 hours as needed. Doses greater than 400 mg have not provided greater relief of pain. *Indomethacin (Indocin®, Indocin SR®, generic available):* This medication is generally not recommended in the elderly due to increased risk of adverse effects. *Dosing: Osteoarthritis, or ankylosing spondylitis:* NOTE: If minor adverse effects develop as the dosage is increased, rapidly reduce the dose to a tolerated dose and closely observe the patient. If severe adverse reactions occur, discontinue. *Regular-release capsules, suspension (25 mg and 50 mg):* 25 mg PO 2—3 times a day with food or antacids; may increase dose by 25 mg/day PO every 7 days up to 150—200 mg/day. In patients who have persistent night pain and/or morning stiffness,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				administer a large portion of the total daily dose, up to 100 mg/dose, at bedtime. *Sustained-release capsules (75 mg):* Initially, 75 mg PO daily. Use the regular-release capsules to provide a higher dose, if needed. If 150 mg daily is tolerated and is needed, a 75 mg sustained-release capsule PO bid may be used. After the acute phase is under control, attempt to decrease the dosage to the lowest effective dosage or discontinue the drug. *Moderate pain to severe pain including painful shoulder (bursitis and tendinitis) as well as off-label for bone pain: Regular-release capsules, suspension (25 mg and 50 mg):* 75-150 mg/day PO in 3-4 divided doses. Discontinue the drug once the signs and symptoms of the inflammation have been controlled for several days. The usual length of therapy is 7-14 days. *Sustained-release capsules (75 mg)*: 75 mg PO 1—2 times per day. *Ketoprofen 50, 75 mg, Ketoprofen ER 200 mg: Dosing: Osteoarthritis:* Regular release capsule 50mg four times per day or

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				75mg three times per day (max 300mg/day). XR capsule 200mg once daily. *Mild to moderate pain:* Regular release capsule 50mg every 6 to 8 hours (Max 300mg/day); *Ketorolac (Toradol®, generic available):* 10 mg. **[Boxed Warning]:** This medication is not indicated for minor or chronic painful conditions. *Mefenamic Acid (Ponstel®, generic available):* 250 mg. *Mild and moderate pain:* Initially, 500 mg PO followed by 250 mg every 6 hours as needed for no longer than 7 days. (Ponstel® Package Insert) *Meloxicam (Mobic®, generic available):* 7.5, 15 mg. *Dosing: Osteoarthritis:* The usual initial dose is 7.5 mg/day, although some patients may receive additional benefit with an increase to 15 mg a day. The maximum dose is 15 mg/day. *Use for mild to moderate pain is off-label.* (Mobic® Package Insert) *Nabumetone (Relafen®, generic available):* 500, 750 mg. *Dosing: Osteoarthritis:* The recommended starting dose is 1000 mg PO. The

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				dose can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. *Use for moderate pain is off-label.* (Relafen® Package Insert) *Naproxen (Naprosyn®):* delayed release (EC-Naprosyn®), as Sodium salt (Anaprox®, Anaprox DS®, Aleve® [otc]) Generic available; extended-release (Naprelan®): 375 mg. Different dose strengths and formulations of the drug are not necessarily bioequivalent. *Dosing Information: Osteoarthritis or ankylosing spondylitis*: Dividing the daily dose into 3 doses versus 2 doses for immediate-release and delayed-release formulations generally does not affect response. Morning and evening doses do not have to be equal in size. The dose may be increased to 1500

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				mg/day of naproxyn for limited periods when a higher level of analgesic/anti-inflammatory activity is required (for up to 6 months). *Naprosyn® or naproxyn*: 250-500 mg PO twice daily. *Anaprox*: 275-550 mg PO twice daily. (total dose may be increased to 1650 mg a day for limited periods). *EC-Naprosyn*: 375 mg or 500 mg twice daily. The tablet should not be broken, crushed or chewed to maintain integrity of the enteric coating. *Naprelan®*: Two 375 mg tablets (750 mg) PO once daily or two 500 mg tablets (1000 mg) once daily. If required (and a lower dose was tolerated) Naprelan® can be increased to 1500 mg once daily for limited periods (when higher analgesia is required). *Pain: Naprosyn® or naproxyn:* 250-500 mg PO twice daily. The maximum dose on day one should not exceed 1250 mg and 1000 mg on subsequent days. *Anaprox:* 275-550 mg PO twice daily. The maximum dose on day one should not exceed 1375 mg and 1100 mg on subsequent days. *Extended-release Naprelan®:* Not

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				recommended due to delay in absorption. (Naprelan® Package Insert) *Oxaprozin (Daypro®, generic available):* 600 mg. *Dosing: Osteoarthritis:* Two 600 mg caplets (1200 mg total) given PO once daily. The maximum dose is 1800 mg/day (26 mg/kg, whichever is lower). For patients with low body weight (i.e., < 50 kg or 110 pounds), an initial dosage of 600 mg PO once daily is recommended. Patients with severe renal impairment should initiate therapy at 600 mg/day. An increase to 1200 mg can be cautiously increased, but only with close monitoring. For quick onset of action, a one-time loading dose of 1200 to 1800 mg can be given (do not exceed 26 mg/kg). *Mild to moderate pain:* Used off-label. (Daypro® Package Insert) *Piroxicam (Feldene®, generic available):* 10, 20 mg. *Dosing: Osteoarthritis:* 20 mg PO once daily. Adjust dose, as needed. The daily dose may be divided in two doses, if desired. This drug has a long half-life and steady state is not reached

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				for 7-12 days. There is a progressive response over several weeks and therapy effect should not be assessed for two weeks after initiating therapy. *Elderly:* Initially, 10 mg PO once daily. Adjust dose, as needed, up to 20 mg/day. *Pain:* Not recommended. (Feldene Package Insert) *Sulindac (Clinoril®, generic available):* 150, 200 mg. *Dosing Information: Osteoarthritis, ankylosing spondylitis*: Initially, 150 mg PO twice daily. Adjust dosage as needed. May increase up to 200 mg PO twice daily depending on patient response. The maximum dose is 400 mg a day. *Mild to moderate pain:* Off label. (Clinoril® Package Insert) *Tolmetin (Tolectin®, Tolectin DS, Tolectin 600mg, generic available): Dosing Information: Osteoarthritis (chronic):* Initially, 400 mg PO three times a day. If needed, adjust dose upward or downward after 1-2 weeks. Maintenance dosage is usually 600-1800 mg/day PO in 3-4 divided doses. (Max dose is 1800mg/day). Symptomatic improvement

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				may occur within 7 days, with progressive improvement during successive weeks of therapy. (Clinical Pharmacology, 2008) (Lexi-Comp, 2008)**"**
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***NSAIDs(non-steroidal anti-inflammatory drugs)***	Commenter indicates that often it is difficult to tell whether or not a specific medical procedure or drug is being recommended or not recommended, and if recommended, under what circumstances, how frequently, how intensely and for how long (for example *NSAIDs*). Commenter adds that without this information, the guidelines will not be successful in ensuring the most effective treatment for injured employees.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** As indicated in connection with the comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on the same individual treatment guideline of "NSAIDs (non-steroidal anti-inflammatory drugs)" above, ODG has conducted its own evidence-based review and has updated the guideline. DWC agrees with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. Commenter claims that the guideline is not clear as "it is difficult to tell whether or not a specific medical procedure or drug is being recommended or not recommended, and if recommended, under what circumstances, how frequently, how intensely and for how long (for example *NSAIDs*)." DWC **disagrees.** Commenter's interpretation of the guideline is incorrect. With respect to the specific individual treatment guideline of NSAIDs, the guideline is clear regarding the class of drugs	See action taken in connection with comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***NSAIDs (non-steroidal anti-inflammatory drugs)*** above

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			that are recommended, and refers the reader to specific sections in the guidelines concerning specific drug agents. It is noted that the revised version being adapted has consolidated these drugs agents into one section. Moreover, the guidelines discuss the duration (e.g., short term v. long term) and appropriate dosage and frequency.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***NSAIDs (non-steroidal anti-inflammatory drugs)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first two sentences, "Recommended for acute pain, acute LBP, short-term pain relief in chronic LBP, and short-term improvement of function in chronic LBP. There is no evidence of long-term effectiveness for pain or function."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***NSAIDs (non-steroidal anti-inflammatory drugs)***	Commenter references the ***NSAIDs (non-steroidal anti-inflammatory drugs)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended for acute pain, acute LBP, short-term pain relief in chronic LBP, and short-term improvement of function in chronic LBP. There is no evidence of long-term effectiveness for pain or function. There is conflicting evidence that NSAIDs are more effective that acetaminophen for acute LBP. (van Tulder, 2006) There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain in this condition. (Namaka, 2004) See NSAIDs, GI symptoms & <u>renal</u> cardiovascular	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** With regard to the comment raising the GI symptoms & renal cardiovascular risk of the individual treatment topic guideline of NSAIDs (non-steroidal anti-inflammatory drugs), see response to comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, NSAIDs (non-steroidal anti-inflammatory drugs), above. **Disagree** with commenter's remaining suggested edits to the	See action taken in connection with comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***NSAIDs (non-steroidal anti-inflammatory drugs)*** above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	risk. See also Anti-inflammatory medications and Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) Decrease in osteogenesis, heterotopic bone formation."		guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***NSAIDs, GI symptoms & cardiovascular risk***	Commenter states that according to Congress, the first decade of the 21st century has been designated as the "decade of pain." Commenter states in many ways this is the case. Commenter indicates that during the last eight years, the joint commission on accreditation of health organizations has added a pain scale as a vital sign. Commenter adds that expenditures per capita on back pain per a recent analysis printed in the Journal of the American Medical Association, shows a 100% increase on monies spent over those without back pain. Commenter states that in the intervening five years since the JC AHO added pain as a vital sign, yearly overdoses from narcotics causing complications including death, had increased to 25,000 cases per year. Commenter states that in the same period, expenditures for narcotics now exceed $1.5 billion a year representing almost 1% of the total health-care expenditures of the United States. Commenter indicates that according to CNN, citing a recent water quality analysis, these drugs are finding their way into the municipal water supply across the nation. Commenter indicates that the same analysis printed in the February edition of JAMA, shows a disproportionate increase in Narcotic prescriptions and the concurrent and equal decrease in Cox two inhibitors prescriptions. Commenter states that the same analysis concludes that patients are doing exactly 0% better in terms of back to work and quality	Michael H. Verdolin, M.D., Medical Director, Pain Control Associates of San Diego August 11, 2008	**Agree in part.** ODG has conducted its own evidence-based review and has updated the individual treatment guideline topic of "NSAIDS (non-steroidal anti-inflammatory drugs)." The revised guideline now addresses commenter's concerns regarding long term effects of NSAIDs to the GI and cardiovascular systems. See response to comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***NSAIDs (non-steroidal anti-inflammatory drugs)*** above. Moreover, ODG has revised its individual treatment topic guideline for "Celebrex®," which is the brandname for celecoxib, the COX-2 selective inhibitor drug which commeter argues is "the only medication NSAID on the market that does not interfere with the antiplatelet	See action taken in connection with comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***NSAIDs (non-steroidal anti-inflammatory drugs)*** above. See also, modified Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Celebrex®:*** **"Celebrex®** Celebrex® is the brandname for celecoxib, and it is produced by Pfizer. Celecoxib is a non-steroidal anti-inflammatory drug

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	of life. Commenter adds that the diminished prescriptions for Cox 2 inhibitors occurred in 2003 when the report of the Grahm study appeared in The Lancet. Commenter indicates that this analysis of Kaiser Permanente data demonstrated an overall risk of 300% over baseline for sudden cardiac death in patients taking Vioxx. Commenter states that the very same data also demonstrated with statistical validity ($p<0.05$) that common household over the counter ibuprofen and naprosyn carried somewhere between a 15 and 20% increase over baseline risk of sudden cardiac death. Commenter adds that interestingly, and without reaching statistical significance, the only Cox 2 inhibitor left on the market, Celecoxib, was less than baseline. Commenter states that while no one would argue a cardio-protective effect, one should consider that the number of test subjects in the population was 1.3 million enrollees. Commenter adds that the FDA led a controversial and well-publicized review of the data, which now infamously led to the withdrawal of Vioxx from the market. Commenter states that there was an attempt to link all Cox 2 inhibitors to this cardiac risk, despite the contradictory data. Commenter states that since this time, a number of studies have implicated non-specific cox inhibitors like naproxen and ibuprofen as further cardiac risky drugs. Commenter states that specifically, these drugs all cause hypertension, water retention, gastric mucosal breakdown, and interference with the anti-platelet effects of prophylactic aspirin. Commenter indicates that at the same time these drugs enhance the bleeding potential in patients taking plavix and coumadin. Commenter indicates that this significantly raises the risk for intracranial bleeding, hemorrhagic stroke, and death by ruptured gastric ulceration. Commenter states that the only medication NSAID on the market that does not interfere with the antiplatelet activity of aspirin and is bleeding neutral in the		activity of aspirin and is bleeding neutral in the operative period. ODG has modified its guideline for Celebrex®" to state that "[u]nlike other NSAIDs, celecoxib does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures." DWC **agrees** with the ODG's updated version of its guideline for Celebrex® dated October 23, 2008 and proposes to adopt the updated version in its adapted version of its chronic pain medical treatment guidelines. The revised guideline is set forth in the action column for the benefit of the regulated public. DWC, **disagrees**, however, with commenter's suggestion that celecoxib be indicated as "a first-line choice in the treatment of injured workers." The purpose of the chronic pain medical treatment guidelines is to provide treating physicians sufficient evidence-based medical information to allow them to make educated decisions in treating their patients, not dictate their treatment.	(NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. See Anti-inflammatory medications. See NSAIDs (non-steroidal anti-inflammatory drugs) for specific patient decision-making criteria. Unlike other NSAIDs, celecoxib does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures."

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	operative period is celecoxib. Commenter indicates that the value of reduced gastric bleeding is further enhanced when combined with interventional procedures such as epidural steroid injections. Commenter explains that this is because steroids also increase the risk of gastric mucosal breakdown, this effect is only compounded by relying on so-called first line NSAIDs which are cox non-specific. Commenter requests that for all these reasons, the panel consider Celecoxib as a first-line choice in the treatment of injured workers. Commenter indicates that this is especially the case when patients are being considered for surgical intervention or interventional pain procedures. Commenter opines that this should be considered the standard of good care in the community.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***NSAIDs, GI symptoms & cardiovascular risk***	Commenter references the ***NSAIDs, GI symptoms & cardiovascular risk*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommend with precautions as indicated below." "Clinicians should weigh the indications for NSAIDs against both GI renal and cardiovascular risk factors." "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions." "Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen,	Robert L. Barkin, PharmD, M.B.A.	**Agree in part.** With regard to the comment raising the GI renal and cardiovascular risk factors of the individual treatment topic guideline of NSAIDs (non-steroidal anti-inflammatory drugs), see response to comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***NSAIDs (non-steroidal anti-inflammatory drugs)*** above. **Disagree** with commenter's remaining suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language.	See action taken in connection with comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***NSAIDs (non-steroidal anti-inflammatory drugs)*** above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	nabumetone, naproxen, etc.)." "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 mg four times daily) [not for use in women of child bearing age – will abort fetus.] or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." "Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007)" "Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia (i.e., oxymorphone). If long-term or high-dose therapy is required, naproxen appears to be the preferred choice of NSAID. Progressive medications include introducing an NSAID with Cox-2 activity. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007)"			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines does not recommend ***Nucleoplasty***. Commenter adds that the guidelines quote company sales literature. Commenter further adds that the second paragraph makes absolutely no sense. Commenter questions the necessity of a discussion of number needed to treat in the	James E. Lessenger, M.D. August 4, 2008	**Agree in part.** ODG performed its own evidence-based review. ODG deleted the second paragraph from its guideline as unnecessary. DWC agrees with ODGs update of its individual treatment guideline on "Nucleoplasty," which is adapted	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Nucleoplasty*** has been modified as follows:

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Nucleoplasty	nucleoplasty section. Commenter adds that the ACOEM Chronic Pain Update does not recommend ***Nucleoplasty***, and indicates that the subject is covered in chapter 12.		into the MTUS. DWC **disagrees** with the remaining comments as they do not address the substance of the proposed regulations. Commenter's statement that the guidelines "quote company sales literature" takes the sentence out of context as the sentence is intended to describe the procedure, and the individual treatment topic is not recommended whether or not the company literature is used to describe the procedure. Moreover, Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "nucleoplasty" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	**"Nucleoplasty** Not recommended. Given the extremely low level of evidence available for Nucleoplasty (Coblation Nucleoplasty), and the lack of clinical trials, it is recommended that this procedure be regarded as experimental at this time. (Manchikanti, 2003) (Boswell, 2007) (ArthroCare Corp, Sunnyvale, CA, introduced the Micro DisCoblator in 2003 to enable minimally invasive disc decompression. Total 2003 Revenue $119 million. Company literature: "The Nucleoplasty procedure uses a minimally-invasive catheter to create a pathway into the disc. Radio wave signals are sent through the transmitter into the nucleus of the herniated disc. The radio waves produce a low-temperature ionized gas that breaks up molecular bonds in the spongy nucleus, removing tissue volume. The Nucleoplasty procedure uses an FDA-cleared device, and is a clinically proven treatment with over 20,000 patients treated."

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				"~~Number needed to treat (NNT) Recommended as a measure of absolute risk in evaluating drug therapies. This is the average number of patients that need to be treated in order to have improvement in one patient. As an example, for every 4 patients treated with neuropathic pain, pain relief described as good is found in 1 patient. The NNT is a useful and relatively simple tool for practicing evidence-based medicine. This calculation can be applied to intervention studies and reflects the number of additional patients who need to receive an intervention to prevent 1 additional outcome. In this recent study, using NNT was superior to achieve participant consent versus other explanations. (Halvorsen, 2007)~~"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Nucleoplasty***	Commenter makes reference to the second paragraph of the text under the treatment guideline for Nucleoplasty. Commenter indicates that the second paragraph under this guideline is confusing and seems out of place. Commenter states that the paragraph needs clarification as to relevance.	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Agree**. DWC **agrees** with the comment that the the second paragraph under this guideline is out of place. This is a clerical error. The second paragraph of this guideline belongs to the individual treatment guideline topic titled "Number needed to treat (NNT)." This guideline was not included in	See action taken in connection with comment submitted by Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain

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			the chronic pain medical treatment guidelines because the subject was "informative and or educational in nature." The explanation for removing the individual treatment guideline topic "Number needed to treat (NNT)," is set forth in Initial Statement of Reasons-Appendix A, page 7, which states in pertinent part as follows: "b. ODG individual treatment topics not included in the chronic pain medical treatment guidelines as they are informative and/or educational in nature "The ODG chapter on pain contains various individual treatment topics that are informative and/or educational in nature. Although informative, these concepts are not treatment topics and do not substantively add to the overall utility of the chronic pain medical treatment guidelines. Moreover, these concepts/definitions are either discussed in part in the introduction of the chronic pain medical treatment guidelines or were determined not to serve a purpose in the guidelines and the MTUS. Further, because the chronic pain medical treatment guidelines are primarily used to assist in the provision of medical treatment by offering an analytical	Intervention and Treatments, ***Nucleoplasty,*** above**.**

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			framework for the evaluation and treatment of injured workers and to help understand what treatment has been proven effective, DWC determined that streamlined guidelines would better serve the public. Accordingly, the ODG chapter on pain individual treatment topics not included in the chronic pain medical treatment guidelines are as follows: *** Number needed to treat (NNT)" *** The paragraph has been removed from the guideline due to clerical error.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Nucleoplasty***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Oral morphine***	Commenter references the Oral morphine treatment guideline and offers the following amendment as reflected by the underlined language: "Not recommended as a primary treatment <u>for persistent pain</u>. The use of opioid analgesics for chronic non-cancer pain is controversial. One randomized controlled trial found that oral morphine may confer analgesic benefit with a low risk of addiction but is unlikely to yield psychological or functional improvement. (Moulin, 1996) See also Opioids."	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Agree.** ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "Oral morphine." Moreover, ODG has accepted commenter's edited language related to "persisten pain." Thus, the first sentence in the guideline has been modified to state: "Not recommended as a primary treatment for persistent pain." DWC **agrees** with the updated	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Oral morphine, is modified as follows: "**<u>Oral morphine</u>** "<u>Not recommended as a primary treatment for persistent pain. The use of</u>

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			version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	opioid analgesics for chronic non-cancer pain is controversial. One randomized controlled trial found that oral morphine may confer analgesic benefit with a low risk of addiction but is unlikely to yield psychological or functional improvement. (Moulin, 1996) See also **Opioids**."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Oral morphine***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first two sentences, "Not recommended as a primary treatment. The use of opioid analgesics for chronic non-cancer pain is controversial."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Oral morphine***	Commenter references the ***Oral morphine*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: ~~Not recommended as a primary treatment.~~ The use of opioid analgesics (oxymorphone, morphine) for chronic non-cancer pain is not controversial. One randomized controlled trial found that oral morphine may confer analgesic benefit with a low risk of addiction but is unlikely to yield psychological or functional improvement. (Moulin, 1996) See also Opioids.	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter states that opioids are "recommended as the standard of care" for chronic nocioceptive pain (p. 47). Commenter states that the specific occupationally-related diagnoses, for which the	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** Commenter appears to state that the statement "opioids are recommended as the standard of care for chronic nociceptive	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and

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Part 2. Pain Intervention and Treatments ***Opioids***	recommendation is made, however, are not stated. Commenter notes that cancer generically is used as the example. Commenter states that the proposed text then goes on to say that chronic pain (again no diagnosis cited) can be a mixture of nocioceptive and neuropathic pain. Commenter indicates that no reference is cited for this statement. Commenter states that the section implies that opioids are recommended for entities such as low back pain and generalized pain. Commenter notes that on p.53, the proposed text states that opioids are not recommended for the first line therapy of neuropathic pain. Commenter further notes that on page 52, the text recommends opioids for neuropathic pain that has not responded to antidepressants and anticonvulsants.		pain" as contained in the individual treatment guideline topic on "Opioids" is not sourced. Commenter also argues that the individual treatment guideline topic on "Opioids" contains no reference to the statement that "chronic pain can be a mixture of nociceptive and neuropathic pain." Commenter is incorrect; the guidelines indicate that these statements are from the World Health Organization (WHO step-wise algorithm). Commenter states that the individual treatment guideline topic on "Opioids" "implies that opioids are recommended for entities such as low back pain and generalized pain;" that the "text states that opioids are not recommended for the first line therapy of neuropathic pain;" and that "the text recommends opioids for neuropathic pain that has not responded to antidepressants and anticonvulsants." Commenter, however, offers no explanation for his comments. The comments are non-responsive as they do not address the substance of the guideline. The chronic pain medical treatment guidelines are clear in their definitions of "nociceptive" and "neuropathic" pain and recognize that these are the pain mechanisms that broadly explain pain (e.g., low back pain).	Treatments, ***Opioids,*** has been modified. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in this column of the chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.

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			Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids***	Commenter states that the grade of evidence for these recommendations is not stated. Commenter notes that the text for opioids for neuropathic pain notes that results are mixed for short and intermediate term studies. Commenter indicates that the diagnoses mentioned include post-herpetic neuralgia, diabetic neuropathy and phantom limb pain. Commenter states that the first two are not occupationally related. Commenter states that in fact, as the American Pain Society, the American College of Physicians, the Ontario Chronic Pain Panels and the proposed text itself (p. 51) note, there is little if any evidence of effectiveness of opioids for chronic pain in clinical trials of more than 70 days duration. Gruener D, Lande SD. *Pain Control in the Primary Care Setting*. Glenview, IL: American Pain Society, 2006. Chou R, Huffman LH. *Guideline for the Management of Low Back Pain in Primary Care*. Philadelphia: ACP, 2007; Smith B. *Chronic Pain Initiative: Report of the Chair of the Chronic Pain Panels.* Toronto: Ontario Workplace Safety and Insurance Board, 2000.] Commenter indicates that the APS/ACP guideline for	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** Commenter raises the issue of the "grade of the evidence" in connection with the individual treatment guideline of development of "opioids." This comment addresses the issue of "medical treatment guidelines" as contained in the definition of this term in section 9792.20(h). These regulations define "medical treatment guidelines" as "the most current version of written recommendations revised within the last five years which are systematically developed by a multidisciplinary process through a comprehensive literature search to assist in decision-making about the appropriate medical treatment for specific clinical circumstances." The ODG guidelines meet DWC's definition of "medical treatment	See action taken in connection with response to comment submitted by same commenter on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

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	low back pain notes that the evidence for opioid efficacy for low back pain is fair, primarily indirect evidence from trials of patients with other pain conditions (Table 2). Commenter states that the text states that observational studies tend to demonstrate improvement in function but there is a high dropout rate. That would reduce the quality rating of an already lower quality study design. Commenter indicates that later in the same paragraph the text cites the 2007 Martell systematic review as stating that there is no evidence that opioids showed long term benefit or functional improvement for chronic low back pain. Commenter states that in the proposed text (p. 51) there are several guidelines for the use of opioids for CNMP, but that they have not been evaluated in clinical practice. While guidelines are not considered to be evidence in EBM, the lack of evaluation in practice suggests that their utility is unknown. Commenter believes that this suggests that the grade of evidence were the MTUS rating system to be used, would be I = insufficient evidence.		guidelines," as set forth in the statute. Moreover, ODG is not required to use the same rating methodology as that used by the DWC in its regulations. DWC acknowledges that the ODG guidelines do not contain the same MTUS methodology. The strength of evidence as adopted in § 9792.25(c) is not applicable to the DWC selection of guidelines to adopt into the MTUS. This is necessary because there is no consensus of a specific evidence rating system, and the ACOEM rating system is unique to ACOEM. If DWC were to only use ACOEM's rating system in its evaluation of guidelines to supplement the MTUS, DWC would be precluded from using any guidelines and would be limited solely to the ACOEM guidelines. The Labor Code allows for the use of other guidelines as Labor Code section 4604.5(e) provides that "for all injuries not covered by the … official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence-based medical treatment guidelines generally recognized by the national medical community and that are scientifically based." Furthermore, DWC determined that the ODG guidelines met the	

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			requirements of the statute based on the findings of the 2005 RAND Report as stated in the ISOR, p. 40. As previously indicated RAND used the AGREE Instrument to evaluate the ODG guidelines. (2005 RAND Report, at p. xix.) The Agree Instrument addresses six domains that suggest an unbiased guideline (AGREE Collaboration, 2001). These six domains include Rigor of Development, which determines "whether developers used systematic and explicit methods to search for evidence and formulate recommendations, considered potential health benefits and risks, had the guideline externally reviewed, and provided an updating plan." The 2005 RAND Report rated the ODG's Rigor of Development "very good." (2005 RAND Report, at p. xx.) ODG's Appendix B—ODG Treatment in Workers' Comp, Methodology Description Using the AGREE Instrument, which has been added to the rulemaking file, describes ODG's Rigor of development, in relevant part, as follows: "ODG Treatment is based on a comprehensive and ongoing medical literature review with preference given to high-quality systematic reviews, meta-analyses and clinical trials." For the reasons set forth above, DWC believes that	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			the individual treatment guideline topic of *"Opioids"* meets the requirements of the statute and the regulations. Moreover, commenter indicates that the individual treatment guideline topic on "opioids" contains diagnoses, which include "post-herpetic neuralgia, diabetic neuropathy and phantom limb pain" and that the first two diagnoses are not occupationally-related. Although these diagnoses are not occupationally-related, they are disease models for neuropathic pain and the evidence-base is derived from these models. This does not mean that these diagnoses are not relevant in the development of the body of evidence. Nevertheless, ODG has conducted its own evidence-base review, and has updated the individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	
9792.24.2(a)	Commenter states this section (pp. 47-51) is not	Jeffrey S. Harris,	**Disagree.** See response to	See action taken in

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Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, criteria for use***	labeled with a strength of evidence. Commenter further states the section appears to be amalgamations of state, society and VA guidelines. As guidelines are not considered primary evidence, this section should be labeled I or consensus.	M.D. August 11, 2008	comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008 on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Opioids, above.	connection with response to comment submitted by Harris, M.D., dated August 11, 2008 on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, long-term assessment***	Commenter states this section (pp. 57-58) is not labeled with a strength of evidence. Commenter further states the section appears to be amalgamations of state, society and VA guidelines. As guidelines are not considered primary evidence, this section should be labeled I or consensus.	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** See response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008 on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Opioids, above. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	See action taken in connection with response to comment submitted by Harris, M.D., dated August 11, 2008 on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain	Commenter states that recommendations in evidence-based medicine are supposed to discuss the balance between benefits and harms of proposed treatments. Commenter indicates that this is reflected in the MTUS methodology. Commenter opines however,	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** See response to same commenter on 9792.24.2(a) Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments,	See action taken in connection with response to comment submitted by same commenter on Section 9792.24.2(a), Chronic Pain

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Intervention and Treatments ***Opioids***	that this discussion, and the synthesis of evidence from which the discussion follows (rather than simply listing and briefly describing studies and other materials) is often absent from important sections of the proposed guideline. Commenter indicates that the opioids section (pp. 46-62) is illustrative. Commenter notes that specifically, the discussion is not organized into harms and benefits, and how the conclusion of "recommended" was reached is not explained. Commenter also notes that who reached that recommendation is also not disclosed. Commenter opined that the public would be better informed if the text were organized into sections on harms and on benefits, and the logic of the balance leading to the recommendation were then explained. Commenter states that as noted in various parts of the material on opioids and the APS publication previously cited, harms of opioids include constipation, somnolence, hyperalgesia, hypogonadism, abuse, persistent mental clouding, upper GI distress, urinary retention, swelling, itching, immune system dysfunction and a host of other less common problems. Commenter indicates that while not randomized controlled trials, high quality retrospective claims studies demonstrated that increasing opioid use is associated with more disability and higher costs. Commenter offers the following bullet points in support of his comments: • Commenter states that opioid use in the acute phase of low back pain increased the length of disability, length of medical care, risk of surgery and late opioid use in proportion to the dose of opioids used. [Webster BS, Verma SK, Gatchel RJ. Relationship between Early Opioid Prescribing for Acute Occupational Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery and Late Opioid Use. Spine, 2007; 32(19): 2127-2132.] • Commenter states workers with occupational low back pain without signs of nerve root compression		Opioids, above. Moreover, **disagree** with commenter's criticism on the organization of the guideline because it is not organized in terms of "benefits and harms." The guideline is organized in a logical, applicable manner consistent with the rest of the document. The guideline provides information about what to do prior to prescribing, how to conduct a trial, and how to determine when you have problems such as substance dependence. This format is more intuitive for the pain clinician. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC agrees with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

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	receiving more than one prescription or 240 morphine equivalent milligrams had higher costs and longer lengths of disability. Workers receiving seven or more opioid prescriptions were 2.7 times more likely to be off work and had 4.7 times more days off work. [Swedlow A, Gardner LB, Ireland J, Genovese E. Pain Management and the Use of Opioids in the Treatment of Back Conditions in the California Workers' Compensation System. Oakland, CA: CWCI, 2008.] Commenter states that opioids do reduce pain, but as noted in the APS/ACP guideline, the net benefit in terms of pain relief is "moderate," or a mean 10-20 points on a 100 point visual analog scale (VAS). A 30 point improvement is generally considered clinically significant. Commenter indicates that given this high adverse effect profile and sub-clinical benefit, there is serious question that opioids should be recommended, especially in a non-specific manner. Commenter adds that a number of professional societies and medical boards advise caution in using opioids for musculoskeletal or other NMCP, and suggest that they be used only as a part of a multidisciplinary rehabilitation program. Commenter states that these opinions are not reflected in the proposed text.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids***	Commenter addresses the *organization* of the opioids treatment guideline. Commenter states that the sections entitled "Opioids, criteria for use" (pp 47-51) and "Opioids, long term assessment" (pp 57-58), the section on pain treatment agreements, and the section on steps to avoid misuse/addiction, all contain similar material that could be combined and better organized for the busy clinician. Commenter states that these sections contain a number of internal contradictions. Commenter also notes that these sections also suggest assessment of likelihood of improvement, likelihood	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** See response to same commenter on 9792.24.2(a) Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Opioids, immediately above.	See action taken in connection with response to comment submitted by same commenter on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

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	of abuse or adverse outcome, whether the pain is neuropathic or nocioceptive, whether there are underlying psychological issues, the likelihood of weaning from opioids if there is no improvement, and other issues but do not explain how to make such assessments. Commenter indicates this is not at all helpful for clinicians who need evidence-based recommendations to optimize the quality of care. Commenter indicates that the third paragraph under the heading "Opioids for Chronic Pain" states that opioids may be added to NSAIDs and acetaminophen if NSAIDS and acetaminophen are not effective. Commenter states that other sections of the proposed guideline recommend anti-depressants and antiepileptic medications for chronic pain. Commenter indicates that there is no sequencing, no definition of effective, and no clear criteria for patient selection in this section to guide the clinician. Commenter states that there are three separate sections on the use of anti-depressant medication for chronic pain (pg. 11-13). Commenter states that they contradict each other somewhat. Commenter indicates that most of the conditions discussed are not work related. Commenter states that the strength of evidence is not given. Commenter indicates that while harms are listed, the balance of harms and benefits is not overtly discussed, nor is the logic for the recommendations stated. Commenter notes that it is interesting to note that the APS guideline previously cited concluded that "SSRIs have poor evidence for analgesic efficacy." Commenter continues that the section on nonneuropathic pain noted only a slight effect of anti-depressants on low back pain. Commenter indicates that many drugs are recommended for off-label use. He notes that			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Gabapentin, for example, is recommended but not FDA approved for fibromyalgia (again not a work-related condition). It is only FDA approved for post-herpetic neuralgia. Commenter adds that the discussion of antidepressants lists a number of non-occupational diagnoses. Commenter notes again that the strength of evidence and the balance of risks, harms and benefits are not stated.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids***	Commenter states that ACIC members believe that in many cases, opioids are being used too soon in treatment plans. Commenter adds that while this draft seems to be more reflective of this approach in the opioid discussion, it is not in discussions of other treatment and modalities.	Keith Bateman, Vice President Property Casualty Insurers Association of America August 12, 2008	**Disagree.** The meaning of the comment is unclear. The comment does not specifically address the substance of the regulations or the individual treatment topic guideline on opioids. Commenter appears to indicate that pursuant to this guideline, opioids are used "too soon." The individual treatment guideline topic of "opioids" is clear that the use of opioids is recommended following a strict criteria recognizing when the benefit of use outweighs the potential harms. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			applicable.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids***	Commenter states that the Opioids treatment guideline in the DWC Chronic Pain Medical Treatment Guidelines is 15 pages and thorough. Commenter observes that the treatment guideline includes an entire section lifted from a State website. Commenter adds that the Opioids treatment guideline in the ACOEM Chronic Pain Update contains 6 recommendations, 1 table, and the references are: 46 high quality RCTs, 13 systemic reviews, 5 reviews, 3 guidelines, 1 low quality RCT, 5 others. Commenter also notes that the appendix is over 40 pages (plus references), and is comprehensive.	James E. Lessenger, M.D. August 4, 2008	**Disagree** with the comment as it does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guidelines on the individual treatment topic of "Opioids" is not clear as it does not address the substance of the guideline. Commenter offers no substantive suggestion to improve the guideline. Moreover, commenter's reference to "Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC]" guideline and his comment that the "guideline includes an entire section lifted from a State website," is misplaced. The section references the CURES program in California and gives appropriate credit and reference to the government agency involved in the program. The website provides the address where more information may be obtained by physicians who encounter patients with risk factors for drug abuse. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, criteria for use***	Commenter references the ***Opioids, criteria for use*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Therapeutic Trial of Opioids 1) Establish a Treatment Plan. The use of opioids should be part of a treatment plan that is tailored to the patient (patient specific/patient centered). Questions to ask prior to starting therapy: (a) Are there reasonable alternatives to treatment, and have these been tried for therapeutic trial? (b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications? (c) Is there likelihood of abuse (diversion, trafficking) or an adverse outcome? See Substance abuse (tolerance, dependence, addiction). (d) Ask about ~~Red~~ Cautionary Flags indicating that opioids may not be helpful in the chronic phase: (1) Little or no relief with opioid therapy in the acute and	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	subacute phases. (2) The patient has had a psychological evaluation and has been given a diagnosis of somatoform disorder. (3) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression), somatic pain complaints manifested by MDD C2 GAD. (e) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision utilizing [illegible] urine drug testing (UPLC [ultra performance liquid chromatograply]/MS/MS). 2) Steps to Take Before a Therapeutic Trial of Opioids: (a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain. (b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics (including tramdadol). (c) Before initiating therapy, the patient and clinician should jointly set goals, and the continued use of opioids should be contingent on meeting these goals.			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument ~~or~~ with numerical rating scale. See Function Measures. (e) Pain related assessment should include history of pain treatment and effect of pain and function. (f) Assess the likelihood and patient agreement that the patient could be weaned from opioids if there is no subjective or objective improvement in pain complaints and function. (g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained. (h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian. (i) A written consent or pain agreement plan for chronic use is ~~not required but may~~ utilized to make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain. See Guidelines for Pain Treatment Agreement. This should include the consequences of non-adherence.			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(j) Consider the use of a comprehensive urine drug ~~screen~~ testing (LC/MS/MS) UPLC MS-MS to assess for the use or the presence of or absence of prescribed, non-prescribed illegal drugs. 3) Initiating Therapy: (a) Intermittent pain: Start with a short-acting opioid ~~trying~~ prescribing one medication at a time. (b) Continuous persistent pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required (if oxymorphone ER, and oxymorphine immediate release). (c) Only change 1 ~~drug~~ medication at a time for 5 eliminating half liters or for 7 days to evaluate therapeutic and non-therapeutic effects. (d) Prophylactic treatment of constipation should be initiated promptly with opioid medication. (e) If partial analgesia is not obtained, opioids should be discontinued. 4) On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as specifically directed, and all prescriptions obtained from a single pharmacy entity. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing each visit review and			

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	documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain; quality of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) This schedule coupled to clinical urine drug testing periodically (UPLC MS-MS). (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of ~~drug screening~~ clinical urine drug testing or inpatient treatment with issues of abuse, diversion, addiction, or poor pain control.			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion, trafficking). (g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psychiatric/psychological consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. 5) Recommended Frequency of Visits While in the Trial Phase (first 6 months): (a) Every 2 weeks for the first 2 to 4 months (b) Then at approximate 1 ½ to 2-month intervals Note: According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. (California, 1994) 6) When to Discontinue Opioids: See Opioid hyperalgesia. Also see Weaning of Medications. Prior to discontinuing, it should be determined that the patient has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible			

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	indications for immediate discontinuation. The patient should not be abandoned. Except if diversion, trafficking, dementia or paucity of opioids contravene. (a) If there is no overall improvement in function, unless there are extenuating circumstances (b) Continuing pain with the evidence of intolerable adverse effects (c) Decrease in functioning (d) Resolution of pain (e) If serious non-adherence is occurring (f) The patient requests discontinuing (g) Immediate discontinuation has been suggested for: evidence of illegal activity including diversion, prescription forgery, or stealing; the patient is involved in a motor vehicle accident and/or arrest related to opioids, illicit drugs and/or alcohol; intentional suicide attempt; aggressive or threatening behavior in the clinic. It is suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment when the prescribed opioids are in the urine by (CUDT) UPL C/MS his) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances. (h) Some ~~Many~~ physicians may~~will~~ allow one "slip or deviation" from a medication agreement~~contract~~ without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	violations. (i) If there are repeated violations from the medication agreement~~contract~~ or any other evidence of abuse, addiction, or possible diversion it has been suggested that a patient show evidence of a consult with a physician that is trained in addiction to assess the ongoing situation and recommend possible detoxification. (Weaver, 2002) (j) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors, clinical urine drug testing or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision. 7) When to Continue Opioids (a) If the patient has returned to work (b) If the patient has improved functioning and pain (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)"			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, criteria for use***	Commenter states that there are 15 pages on opioids. Commenter further states that although they are well written, non-controversial and frankly "common sense," there is a critical need for some guidance on the use of these medications in the acute, subacute and chronic pain cases. Commenter states that the payors are going to assume that this will be able to be "managed" within utilization review on the basis of this document but he believes the guidelines do not provide the specific parameters to do so.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** Labor Code section 5307.27 requires the Administrative Director to adopt a medical treatment utilization schedule (MTUS) that incorporates evidence-based, peer-reviewed, nationally recognized standards of care that address the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

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	Commenter opines that it is likely that UR may not be the arena necessary to manage this treatment modality and if the committee would come to a consensus on this, it should be clearly stated in the MTUS. Commenter believes that clinically dosing is a function of the individual patient and what might be most useful would be some parameter on the extended use of the medication and some substance to challenge a provider within the UR system regarding this matter.		commonly performed in workers' compensation cases. The chronic pain medical treatment guidelines address the area of chronic pain, which has not been previously addressed by the MTUS. The MTUS is structured to start providing treatment to injured workers beginning with treatment guidelines that address acute injuries that are expected to get better. These injuries are addressed utilizing the body parts chapters found in the clinical topics sections of the MTUS, and the chronic pain medical treatment guidelines do not apply to these cases. When the painful condition does not heal, and if there is no cure for that condition, then the chronic pain medical treatment guidelines apply. Thus, the clinical topics sections of the MTUS provide guidance on the use of opioids medications in the acute, subacute stage, while the chronic pain guideline provide guidance on the use of opioids medication in the chronic stage of the condition. Indeed, the adoption of the individual treatment topic guideline on opioids medications provide a mechanism to avoid unnecessary use of opioids, by providing information about what to do prior to prescribing, how to conduct a trial, and how to determine when there are problems	

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			such as substance dependence. With regard to the comment regarding the specific parameters for utilization review (UR), commenter does not provide an example of the degree of specificity he is requesting from the guidelines, although he recognizes that the text of the regulation on opioids are well written, non-controversial and "common sense." Although commenter questions whether UR is the arena to manage this treatment modality, the DWC via these regulations has determined that UR is the arena for which these guidelines apply. Moreover, the guidelines provide guidance on the parameters for extended use in chronic pain as there is a specific section that explains how to monitor the chronic use of opioids. This section is entitled: "Opioids, long-term assessment." Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC agrees with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart.	

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			Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids for chronic pain***	Commenter references the ***Opioids for chronic pain*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "There are several proposed guidelines for the use of opioids for chronic non-malignant pain, but these have not been evaluated in clinical practice, and selection of the patient that will best respond to this treatment modality remains difficult. (Nicholas, 2006) (Stein, 2000) One of the most recent of these guidelines is the Agency Medical Director's Group (AMDG) Guidelines from Washington State. This guideline includes an opioid dosing calculator. (AMDG, 2007) <u>All calculations must account for incomplete opioid cross tolerance.</u> Outcomes measures: It is now suggested that rather than simply focus on pain severity <u>and merely an [illegible] pain scale for a [illegible] disease</u>, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects."	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids for osteoarthritis***	Commenter references the ***Opioids for osteoarthritis*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Not <u>ever</u> recommended as a first-line <u>acute</u> therapy. Recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "Opioids for osteoarthritis." DWC **agrees** with the updated	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids for osteoarthritis,*** has been revised as follows: **"Opioids for osteoarthritis**

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	NSAIDs or tramadol when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. (Stitik, 2006) (Avouac, 2007) Under study for long-term use. There is a lack of evidence to allow for a treatment recommendation. If used on a long-term basis, the criteria for use of opioids should be followed. See Opioids, criteria for use."		version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. The specific portion of this updated guideline, which is part of the individual treatment guideline topics on "Opioids", is set forth in the action column of the chart for the benefit of the regulated public.	Not recommended as a first-line therapy for osteoarthritis. *Short-term use:* Recommended on a trial basis for short-term use after there has been evidence of failure of first-line non-pharmacologic and medication options (such as acetaminophen or NSAIDs) and when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Weak opioids should be considered at initiation of treatment with this class of drugs (such as Tramadol, Tramadol/acetaminophen, hydrocodone and codeine), and stronger opioids are only recommended for treatment of severe pain under exceptional circumstances (oxymorphone, oxycodone, hydromorphone, fentanyl, morphine sulfate). Benefits of opioids are limited by frequent side effects (including nausea, constipation, dizziness, somnolence and vomiting). (Stitik, 2006) (Avouac, 2007) (Zhang, 2008)

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				Long-term use: Under study for long-term use as there are no long-term trials. There is therefore a lack of evidence to allow for a treatment recommendation. If used on a long-term basis, the criteria for use of opioids should be followed. See Opioids, criteria for use. *Opioids in general:* A recent meta-analysis found that opioids were more effective than placebo for reducing pain intensity. The benefit for physical function was small and was considered questionable for clinical relevance. Lack of benefit for function may be due to lack of anti-inflammatory effect for this class of medications and presence of side effects such as dizziness and drowsiness. Adverse events in general may limit the benefit of opioids as this same study found that out of every five patients that received opioids, one discontinued the medication due to an adverse event. These adverse events included epigastric pain, nausea, vomiting, constipation, dry mouth,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				dizziness, somnolence and headache. Weaker opioids were found to be less likely to produce adverse effects than stronger opioids such as oxycodone, Fentanyl or morphine. No conclusion can be made on how opioids compare to other available pharmacologic treatment due to limited studies. (Avouac, 2007) Specific Opioids: *Tramadol:* A recent Cochrane review found that this drug decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline). Adverse events often caused study participants to discontinue this medication, and could limit usefulness. There are no long-term studies to allow for recommendations for longer than three months. (Cepeda, 2006) Similar findings were found in an evaluation of a formulation that combines immediate-release vs. extended release Tramadol. Adverse effects included nausea, constipation,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				dizziness/vertigo and somnolence. (Burch, 2007)".
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids for osteoarthritis***	Commenter references the ***Opioids for osteoarthritis*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Tramadol: A recent Cochrane review found that this drug decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline). Adverse events often caused study participants to discontinue this medication, and could limit usefulness. ~~There are no long term studies to allow for recommendations for longer than three months. (Cepeda, 2006)~~ A recent review reveals benefit in osteoarthristis (Chronic Pain of Osteoarthritis: Considerations for Selecting an Extended-Release Opioid Analgesic. American Journal of Therapeutics. 15(3):241-255, May/June 2008. *Gibofsky, Allan MD, JD, FACP, FCLM 1,2*; Barkin, Robert L MBA, PharmD 3,4*"	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless ODG conducted its own evidence-base review and has updated its individual treatment guideline topic on "Opioids for osteoarthritis." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	See action taken in connection with comment submitted by Robert L. Barkin, PharmD, M.B.A., on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids for osteoarthritis,*** above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, dealing with misuse & addiction***	Commenter references the **Opioids, dealing with misuse & addiction** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommend that, if there are active signs of diversion, misuse, and addiction these concerns should be addressed immediately with the patient. If there are active signs of relapse to addiction, or new-onset addiction, these patients should be referred to an addictionologist immediately. It has been suggested that most chronic pain problems will not resolve while there is active and ongoing alcohol, illicit drug, or prescription drug abuse. (Weaver, 2002) Some ~~Many~~	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC agrees with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	physicians will allow one "slip or deviation" from a medication agreement ~~contract~~ without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the mandatory consequences of repeat violations. If there are repeated violations from the medication agreement ~~contract~~ or any other evidence of abuse, addiction, or possible diversion, it has been suggested that a patient show evidence of consultation with a physician boarded ~~trained~~ in addiction treatment for assessment of the situation and possible detoxification. It is also suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances when in fact the controlled substance has been [illegible] by clinical urine drug testing (LC/MS/MS). (Weaver, 2002) When less serious warning signs arise, the following have been recommended (after making sure that there is no change in the patient's condition that has introduced a need for additional treatment): (a) Initiate closer monitoring with more frequent visits; (b) Consider limitations in the amount of medication prescribed at any one time; & (c) Re-review the clinic policy on controlled substance use and the medication agreement ~~contract~~. (Weaver, 2002) (Chabel, 1997) In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to California physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code section 2241.5. (California, 1994)"		voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, differentiation: dependence & addiction***	Commenter references the ***Opioids, differentiation: dependence & addiction*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "1) The Prescription Drug Use Questionnaire: (Compton, 1998) This is a tool still in development, and it has not been validated. Variables found to be positive for individuals with a substance disorder were the following: (a) Belief by the individual that he/she was addicted; (b) Drug seeking behaviors (having more than one provider, increasing analgesic dose or frequency, calling in for premature ~~early~~ refills, and obtaining analgesics from the ER or acute care centers); (c) Using analgesics to relieve symptoms other than pain (insomnia, anxiety, depression); (d) supplementing analgesics with alcohol or other psychoactive drugs; & (e) Having been terminated from care by a physician or dentist. The three variables that correctly classified > 90% of addicts were: (1) A tendency to consider oneself addicted; (2) A preference for the route of administration; & (3) A tendency to increase opioid dose."	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC agrees with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, differentiation: dependence & addiction***	Commenter references ***Opioids, differentiation: dependence & addiction*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "3) Chelminski multi-disciplinary pain management program criteria: (Chelminski, 2005) Criteria used to define serious substance misuse in a multi-disciplinary pain management program: (a) cocaine or amphetamines on urine toxicology screen (this is presumptive only – not confirmed UPLC-MS/MS) (positive cannabinoid was not considered serious substance abuse in this study); (b) procurement of	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC agrees with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed (nor disclosed)."		23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, indicators for addiction***	Commenter references the ***Opioids, indicators for addiction*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Clinical judgment by a physician trained in recognition of addiction is needed to determine if the patient actually has an addiction disorder. ([illegible]) A history of an addiction disorder does not preclude a patient from being treated with opioids. (Savage, 1999) (Portenoy, 1996) See also Criteria for use of opioids; Opioids, screening for risk of addiction; Opioids, screening for dependence vs. addiction; Opioids, patients at high-risk for misuse; & Substance abuse (tolerance, dependence, addiction)."	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless ODG conducted its own evidence-base review and has updated its individual treatment guideline topic on "Opioids, indicators for addiction" as part of the update of the individual treatment guideline topic on "opioids" update. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2., Pain Intervention and Treatments, ***Opioids, indicators for addiction,*** has been modified as follows: **"Opioids, indicators for addiction** "Recommend screening for indicators below. It is estimated that the prevalence of addictive disorders and/or serious substance misuse in patients with chronic pain may be as high as 30%. (Chelminski, 2005) The prevalence of current substance abuse disorders in patients with chronic back pain ranges from 3% to 43%, with a lifetime prevalence of 54% (but the author warns that these statistics are limited by poor study design and publication bias). (Martell-*Annals*, 2007) In studies of patients in methadone maintenance

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				treatment as many as 44% of patients with chronic pain felt that the use of prescription opioids led to their problems with addiction. (Jamison, 2000) One particular problem is that in patients with substance abuse disorders and chronic pain the detrimental effects of drug use on lifestyle and psychosocial function may be ascribed to chronic pain instead of drug use, making the addiction disorder difficult to diagnose and treat. In addition, intermittent substance abuse withdrawal presents as and/or may cause hyperalgesia and facilitate pain. Another problem is that physicians are not well trained in diagnosing addiction or treating this condition. (Compton, 1998). (Savage, 2002) Clinical judgment by a physician trained in recognition of addiction is needed to determine if the patient actually has an addiction disorder. A history of an addiction disorder does not preclude a patient from being treated with opioids. (Savage, 1999) (Portenoy,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				1996) See also Criteria for use of opioids; Opioids, screening for risk of addiction; Opioids, screening for dependence vs. addiction; Opioids, patients at high-risk for misuse; & Substance abuse (tolerance, dependence, addiction)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, indicators for addiction***	Commenter references the ***Opioids, indicators for addiction*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "4) Adverse behavior: (a) Selling prescription drugs, (b) Forging prescriptions, (c) Stealing drugs, (d) Using prescription drugs is ways other than prescribed (such as injecting oral formulations), (e) Concurrent use of alcohol or other illicit drugs (as detected on urine screens), (f) Obtaining prescription drugs from non-medical sources, (g) absence or non-therapeutic levels of prescribed controlled substances – urine by UPLC MS/MS. (Wisconsin, 2004) (Michna, 2004) (Chabal, 1997) (Portenoy, 1997)"	Robert L. Barkin, PharmD, M.B.A.	**Disagree.** See response to comment submitted by Robert L. Barkin, PharmD, M.B.A., on section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Opioids, indicators for addiction, above.	See action in connection with comment submitted by Robert L. Barkin, PharmD, M.B.A., on section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids, indicators for addiction,*** above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, long-term assessment***	Commenter references the ***Opioids, long-term assessment*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "(c) ~~The standard increase in~~ A recommended dose is 25 to 50% for mild pain and 50 to 100% for severe pain (Wiconsin)."	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, pain treatment agreement***	Commenter references ***Opioids, pain treatment agreement*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended. A written consent or pain agreement for chronic use is suggested and ~~not required but~~ may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain. This type of written document should be obtained prior to initiating opioid therapy. It should be discussed with the patient and family. This plan should be signed and dated and placed in the patient's chart, and include the following:(1) Goals of therapy, (2) Only one provider gives prescriptions, (3) Only one pharmacy dispenses prescriptions, (4) There will be a limit of number of medications, and dose of specific medications, (5) Medications are not to be altered without the prescribing doctor's permission, (6) Heavy machinery and automobile driving is not to occur until drug-induced sedation/drowsiness has cleared, (7) Refills are limited, and will only occur at scheduled appointments, (8) Treatment compliance must occur for all other modalities enlisted, (9) Urine drug	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	[illegible] tests ~~screens~~ may be required (UPLC MS-MS), (10) The patient must acknowledge that they are aware of potential adverse effects of the use of opioids including addiction, (11) Information about opioid management can be shared with family members and other providers as necessary, (12) If opioid use is not effective, the option of discontinuing this therapy may occur, (13) The consequence of non-adherence to the treatment agreement is outlined. (VA/DoD, 2003) ~~(Heit, 2007)~~ The patient is fully informed."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, screening for risk of addiction (tests)***	Commenter references the ***Opioids, screening for risk of addiction (tests)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "e) Been injured after drinking?" "Note: Be aware that many clients are not naïve to questions – how and what to answer"	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless ODG conducted its own evidence-base review and has updated its individual treatment guideline topic on "Opioids, indicators for addiction" as part of its update of the individual treatment guideline on "Opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. The relevant portion of this guideline is set forth in the action column of this chart for the benefit of the public.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids, screening for risk of addiction (tests)*** has been modified as follows: **"Opioids, screening for risk of addiction (tests)** "Recommend screening for the risk of addiction prior to initiating opioid therapy. It is important to attempt to identify individuals who have the potential to develop aberrant drug use both prior to the prescribing of opioids and while actively undergoing this treatment. Most screening occurs after the claimant is already on opioids on a chronic basis, and consists of screens for aberrant behavior/misuse. Recommended screening

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				instruments include the following: "1) *The CAGE Questionnaire:* (Brown, 1995) The most widely used screening tool prior to starting opioids is the CAGE questionnaire. "a) Have you ever felt the need to cut down on your drinking or drug use? "b) Have people annoyed you by criticizing your drinking or drug use? "c) Have you ever felt bad or guilty about your drinking or drug use? "d) Have you ever needed an eye opener the first thing in the morning to settle your nerves? "2) *Cyr-Wartman Screen:* (Cyr, 1988) "a) Have you ever had a problem with alcohol (or drugs)? "b) When was your last drink (or drugs)? "3) *Skinner Trauma Screen*

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				(Skinner, 1984) Since your 18th birthday, have you "a) Had any fractures or dislocations to your bones or joints? "b) Been injured in a road traffic accident? "c) Injured your head? "d) Been injured in an assault or fight (excluding injuries from sports)? "e) Been injured after drinking? "4) *The Screener and Opioid Assessment for Patients with Pain (SOAPP)* (Akbik, 2006) A brief self-report measure to capture important information in order to identify which chronic pain patients may be at risk for problems with long-term opioid medications. The cutoff score has been found with a positive answer of 8 or higher. Five factors were identified on factor analysis labeled 1) history of substance abuse, 2) legal problems, 3) craving medication, 4) heavy smoking, and 5) mood

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				swings. "It is important to note that being at risk does not necessarily indicate that a patient will develop an addiction disorder, or is addicted. ~~A history of an addiction disorder does not preclude a patient from being treated with opioids. (Savage 1999) (Portenoy, 1996)~~ "5) *Opioid Risk Tool* (Kahan, 2006) A brief self-report tool that addresses five factors: (1) Family history of substance abuse; (2) Personal history of substance abuse; (3) Age (between 16 and 45 years); (4) History of preadolescent sexual abuse in females; & (5) Psychiatric history (ADD, OCD, bipolar, schizophrenia, and depression). The tool is gender specific. A history of an addiction disorder does not preclude a patient from being treated with opioids. (Savage 1999) (Portenoy, 1996)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommend ***Optional Psychological Interventions with Opioids for Chronic Pain.*** Commenter states that there is no	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** The individual treatment guideline topic for "Opioids, psychological intervention" is supported by evidence. There is	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D.,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments ***Opioids, psychological intervention***	quality evidence to suggest that psychological interventions used with opioids "improve effectiveness of opioids for chronic pain". Commenter states that such interventions should be considered for clinically significant symptoms of addiction or during weaning. (Chronic Pain Medical Treatment Guideline, Page 58, par 4.)		evidence for (a) Providing ongoing education on both the benefits and limitations of opioid treatment. (b) Emphasizing non-opioid care including self-management techniques, including relaxation, mindfulness meditation, acceptance, and distraction. (c) Emphasizing realistic goals. (d) Avoiding increasing dosages of medications to "chase pain." (e) Encouraging development of strategies for self-regulation of medication misuse, including incorporation of a support group such as friends, family, an identified group (such as a 12-step group or group counseling), and/or individual counseling. See (Naliboff, 2006) In stating that there is no quality evidence to support this guideline, commenter is applying ACOEM grading methodology which is different from ODG's methodology. It is noted that DWC is not required to use ACOEM's grading methology in adopting other guidelines into the MTUS. See, response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a) Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.	dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.
9792.24.2(a) Chronic Pain	Commenter references the ***Opioids, steps to avoid misuse/addiction*** treatment guideline contained in	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as	See action taken in connection with response to

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioids, steps to avoid misuse/addiction***	Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "The following are steps to avoid misuse of opioids, and in particular, for those at high risk of abuse: a) Opioid therapy agreements ~~contracts~~. See Guidelines for Pain Treatment Agreement. b) Limitation of prescribing and filling of all prescriptions to one pharmacy. c) Frequent random complete urine ~~toxicology screens~~ drug testing (UPLC MS-MS) confirmation."		they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioid hyperalgesia***	Commenter references the ***Opioid hyperalgesia*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Definition: Patients who receive opiate therapy sometimes develop unexpected changes in their response to opioids. This may include the development of abnormal pain ~~(hyperalgesia)~~, a change in pain pattern, or persistence in pain at higher levels than expected."	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC agrees with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			action column of the chart when applicable.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Opioid hyperalgesia***	Commenter references the ***Opioid hyperalgesia*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "(6) Psychological issues such as secondary gain, exacerbation of underlying depression or anxiety, and the development of addictive disease, diversion should also be ruled out. Treatment: Suggested treatment for patients with increasing pain (assumes that the patient has had improvement with opioids at some point): (1) It is not unreasonable to give a structure trial of opioid dose escalation to see if pain and function improves. If pain improves, the diagnosis is probable tolerance. If pain does not improve or worsens, this may be evidence of opioid hyperalgesia and the opioid dose should be reduced or actually weaned. (2) Opioid rotation is another option or adding a different opioid for BTP. (3) Use of adjuvant pain medications (ex: NSAID, AED, AD) is recommended when there is evidence of either tolerance or hyperalgesia."	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Nevertheless, ODG has reviewed the evidence-base and has updated its individual treatment guideline on "opioids." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. As the guideline consists of a total of 23 pages, the guideline is too voluminous to set forth in the action column of this chart. Specific portions of the updated guideline will be placed in the action column of the chart when applicable.	See action taken in connection with response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Opioids***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Percutaneous***	DWC's guidelines provides as follows: "Percutaneous electrical nerve stimulation (PENS) [DWC]: Not recommended." Commenter appears to agree with DWC's guideline.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree.**	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
electrical nerve stimulation (PENS) [DWC]				
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Percutaneous neuromodulation therapy (PNT)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Phentalamine infusion test***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language but the following: "This test aids in the diagnosis of SMP (Sympathetically maintained pain)."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Physical Medicine [ODG]***	Commenter states that the recommendation for Physical Medicine on pages 63 and 64 of the Proposed Chronic Pain Treatment Guidelines is very brief. Commenter states that it appears to discuss acute injury. Commenter indicates that there is no discussion of the objective indications for any type of therapy, for example specific weakness or limited range of motion. Commenter indicates that it is a very general discussion of active and passive therapy. Commenter notes that there is no evidence-based assessment of any specific treatment for either form of physical medicine for any specific diagnosis or diagnostic group. Commenter indicates that the recommendations made are apparently general for fading of treatment (unspecified) framed as number of	Jeffrey S. Harris, M.D. August 11, 2008	**Agree in part. Agree** that the individual treatment guideline for Physical Medicine discusses "acute" pain. A reference to "acute" pain contained in the guideline was deleted. The sentence, however, was left intact because it is also applicable to "chronic pain." **Disagree** with commenter's comments regarding the length of the guideline and the comment stating that the discussion of active and passive therapy is very general. These comments do not address the	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Physical Medicine [ODG]*** has been revised as follows: **"Physical Medicine ~~[ODG]~~** "Recommended as indicated below. Passive therapy (those treatment modalities that do not require energy expenditure on the part of

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	visits. Commenter also states that there are then recommendations for myalgia and for 26 visits for CRPS I. Twenty-six visits exceeds the statutory limit of 24 visits.		substance of the guideline. With regard to the comment that "there is no discussion of the objective indications for any type of therapy," it is noted that this comment is incorrect. DWC **disagrees**. The comment addresses the issue of when a treatment is necessary, i.e., a medical indication. The guideline contains specific language that passive therapy is "directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries." Further, active therapy is indicated for "restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort." DWC **disagrees** with the comment that the guideline does not provide for any specific evidence-based review for a specific diagnosis or diagnosis group. For example, the guideline provides examples of CRPS and adds low back. **Agree** that 26 visits exceed the statutory time limitation. Revisions will be made to the guideline accordingly. ODG has conducted its own evidence-based review, and has updated the individual treatment guideline on "***Physical Medicine [ODG]***." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain	the patient) can provide short term relief during the early phases of ~~acute~~ pain treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They can be used sparingly with active therapies to help control swelling, pain and inflammation during the rehabilitation process. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy may require supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			medical treatment guidelines.	assistance or resistance and functional activities with assistive devices. (Colorado, 2002) (Airaksinen, 2006) Patient-specific hand therapy is very important in reducing swelling, decreasing pain, and improving range of motion in CRPS. (Li, 2005) The use of active treatment modalities (e.g., exercise, education, activity modification) instead of passive treatments is associated with substantially better clinical outcomes. In a large case series of patients with low back pain treated by physical therapists, those adhering to guidelines for active rather than passive treatments incurred fewer treatment visits, cost less, and had less pain and less disability. The overall success rates were 64.7% among those adhering to the active treatment recommendations versus 36.5% for passive treatment. (Fritz, 2007) **Physical Medicine Guidelines –** Allow for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				directed home Physical Medicine. **Myalgia** ~~(muscle pain) or~~ **and myositis** ~~(inflammation)~~**, unspecified** (ICD9 729.1): 9-10 visits over 8 weeks **Neuralgia, neuritis, and radiculitis, unspecified** (ICD9 729.2) 8-10 visits over 4 weeks **Reflex sympathetic dystrophy (CRPS~~-I~~)** (ICD9 337.2): 26 visits over 16 weeks"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Physical Medicine [ODG]***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Physical Medicine***. Commenter states that the DWC guideline contains a short, half page discussion on one of the major areas in pain treatment. He further states that it contains only two references. He opines that the recommendation is extremely superficial, and that it presents "physical medicine guidelines" without any citation. He further observes that there is no mention of any specific modality and it is far too general to be of use in utilization review. Commenter adds that the ACOEM Chronic Pain Update recommends ***Physical Medicine***. Commenter observes that the recommendation is 6 pages long, contains 6 recommendations, and 4 modalities.	James E. Lessenger, M.D. August 4, 2008	**Disagree** with the comment as it does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guidelines on the individual treatment topic of "Physical Medicine" is not clear as it does not address the substance of the guideline. Moreover, DWC recognizes that ODG has body part sections and other text concerning physical therapy. Those ODG sections (contained in other ODG chapters) are not adopted into the MTUS as they would not harmonize with the use of the ACOEM Clinical topics as adopted into the MTUS. The omission of specific recommendations in the chronic pain medical treatment guidelines is intended to allow the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Clinical topics section to apply and address the use of modalities or physical treatment methods which are dependent on the area of body that is in pain.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Physical Medicine [ODG]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language but the following: "Recommended as indicated below." Commenter states, however, that this guideline should be deferred to ACOEM and not be part of this chronic pain guideline. The recommendation is not different [from ACOEM] but commenter opines that it would be best to not overlay this portion and supersede ACOEM.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree** with the comment as it does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guidelines on the individual treatment topic of "Physical Medicine" is not clear as it does not address the substance of the guideline. Moreover, DWC recognizes that ODG has body part sections and other text concerning physical therapy. Those ODG sections (contained in other ODG chapters) are not adopted into the MTUS as they would not harmonize with the use of the ACOEM Clinical topics as adopted into the MTUS. The omission of specific recommendations in the chronic pain medical treatment guidelines is intended to allow the Clinical topics section to apply and address the use of modalities or physical treatment methods which are dependent on the area of body that is in pain. Thus, there is no need to "defer this guideline to ACOEM," as requested by the commenter.	None.
9792.24.2(a) Chronic Pain	Commenter states that the guidelines contain items discussed that have no relevance to treatment of	Keith Bateman, Vice President	**Disagree.** Commenter claims that the individual treatment guideline	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Power mobility devices (PMDs)***	chronic pain such as the discussion of power mobility devices found on page 64 of the chronic pain section.	Property Casualty Insurers Association of America August 12, 2008	topic on "Power mobility devices (PMDs)" has no relevance to the treatment of chronic pain. DWC disagrees. There are cases where the "pain" causes a need for the use of a powered wheelchair. To the extent that pain causes that need, and there is a consequential request for a powered wheelchair, the individual treatment guideline topic on "Power mobility devices (PMDs)" applies to address this issue in the chronic pain medical treatment guidelines.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Power mobility devices (PMDs)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Pregabalin (Lyrica®)***	Commenter references the ***Pregabalin (Lyrica®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Pregabalin (Lyrica®) has been associated with weight gain, cognitive changes, euphoria, QTc prolongation, peripheral edema, thrombocytopenia. Dosed based upon creatinine clearance renal function."	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggested edits to the guideline as they are inconsistent with ODG's style and do not substantively improve the guideline language. Moreover, reference is made to the individual treatment guideline topic on "Antiepilepsy (AEDs)." In that guideline, "Pregabalin (Lyrica®)" is discussed and commenter's concerns regarding side effects are addressed. The specific portion of the individual treatment guideline topic on "Antiepilepsy (AEDs)," setting	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			forth the side effects of "Pregabalin (Lyrica®)" states, in relevant part, as follows: "*Side-Effect Profile:* Pregabalin has been associated with many side effects including edema, CNS depression, weight gain, and blurred vision. Somnolence and dizziness have been reported to be the most common side effects related to tolerability. (Tassone, 2007) (Attal, 2006) It has been suggested that this drug be avoided if the patient has a problem with weight gain. (Jensen, 2006)" (At p. 20, Chronic Pain Medical Treatment Guidelines.)	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Prolotherapy***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended." Commenter also states this is addressed in ACOEM but limited to the low back. Commenter opines that it would be good to leave this in the guideline as it addresses more global indications (or non-indications as the case is).	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part. Disagree** with suggested edits**.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. A**gree** with commenter that it is appropriate to keep this guideline in the chronic pain medical treatment guidelines, as its use does not fall under the clinical topics section of the MTUS where the goal is management of the acute condition or to cure the condition. It is in the chronic pain medical treatment guidelines wherein prolotherapy is most likely requested for the	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Prolotherapy***, is modified as follows: **"Prolotherapy** "Not recommended. Prolotherapy describes a procedure for strengthening lax ligaments by injecting proliferating agents/sclerosing solutions directly into torn or stretched ligaments or tendons or into a joint or adjacent structures to create scar tissue in an effort to stabilize a joint. Agents used with

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			patient with chronic pain. It is noted that ODG has conducted its own evidence-base review and has updated the individual treatment guideline topic of "Prolotherapy" to add more citations. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	prolotherapy have included zinc sulfate, psyllium seed oil, combinations of dextrose, glycerine and phenol, or dextrose alone. "Proliferatives" act to promote tissue repair or growth by prompting release of growth factors, such as cytokines, or increasing the effectiveness of existing circulating growth factors. Prolotherapy has been investigated as a treatment of various etiologies of pain, including arthritis, degenerative disc disease, fibromyalgia, tendinitis, and plantar fasciitis. In all studies the effects of prolotherapy did not significantly exceed placebo effects. (Dechow, 1999) (Reeves, 2000) (Yelland, 2004) (BlueCross BlueShield, 2006)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Psychological evaluations***	Commenter states that in the "Psychological evaluations" section on pages 64-65, the second test listed in the California/ODG document is the Millon Behavioral Health Inventory (MBHI). Commenter states that this test was listed in the referenced Colorado document (which he developed – Bruns, 2001), while this test was listed in the Colorado document, the Colorado document stated: "Obsolescent test has been replaced by the MBMD." Commenter states that the MBHI was an obsolete test in 2001 when this document was prepared, and is that much more so now. Commenter states that his concern is that by only listing the MBHI acronym in	Daniel Bruns, PsyD Licensed Psychologist July 18, 2008	**Agree in part.** ODG has performed its own evidence-based review and has updated its individual treatment guideline for "psychological evaluations." ODG determined that the Millon Behavioral Health Inventory (MBHI) was obsolete by the Millon Behavioral Medical Diagnostic (MBMD). With respect to the Battery for Health Improvement (BHI) source ODG has also updated its guideline to	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments ***Psychological evaluations*** has been amended as follows: **"Psychological evaluations** "Recommended. Psychological evaluations are generally accepted, well-

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the California guidelines, without the attached information supplied in the original documents, this seems to recommend this test. Commenter states that it is an ethical violation for a psychologist to use a psychological test that is so far out of date, when a newer and improved version is available (see American Psychological Association ethical principle 9.08 Obsolete Tests and Outdated Test Results). Commenter states he does not know if the California regulations have the intention of attaching the entire Colorado document to their regulations. Commenter states that if not, then this would be a matter of concern for him. Commenter states that overall, by only listing the tests from the Colorado document, and none of the information attached to it, this may convey the wrong message. Commenter adds similar comments with respect to the ***Psychological evaluations*** guidelines regarding the Battery for Health Improvement (BHI). Commenter states that the original source lists BHI 2, which is the newer, more appropriate test, that unless the audience is very familiar with the clinical area could again apply sub-standard care. Commenter adds that a further possibility could result from a payer incorrectly inferring that the BHI 2 test was experimental. (Page 65.) Commenter states that in his opinion, the ACOEM chronic pain guidelines has a clear advantage in the area of psychological evaluations in that it provides not only information about psychological tests in general, as does the Colorado document referenced by California/ODG, but also goes beyond this to provide a lot of additional information. Commenter states that first of all, the ACOEM document identifies much more clearly when psychological testing is indicated. Commenter states that additionally, it offers a		cite the most recent edition of the test listed, thus BHI 2nd ed. - Battery for Health Improvement. DWC **agrees** and has adapted ODG's October 23, 2008 version into its chronic pain medical treatment guidelines. Commenter states that the chronic pain guidelines contain very little discussion on the biopsychosocial aspects of chronic pain. DWC also **agrees in part.** Although ODG discusses the biopsychosocial model in existing sections of ODG, ODG decided to create a new section entitled "Biopsychosocial model of chronic pain" to direct the reader to the various section which cover this topic. **Disagree** with the remaining comments as they do not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guideline on the topic of "psychological evaluations" is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	established diagnostic procedures not only with selected use in pain problems, but also with more widespread use in ~~subacute and~~ chronic pain populations. Diagnostic evaluations should distinguish between conditions that are preexisting, aggravated by the current injury or work related. Psychosocial evaluations should determine if further psychosocial interventions are indicated. The interpretations of the evaluation should provide clinicians with a better understanding of the patient in their social environment, thus allowing for more effective rehabilitation. (Main-BMJ, 2002) (Colorado, 2002) (Gatchel, 1995) (Gatchel, 1999) (Gatchel, 2004) (Gatchel, 2005) For the evaluation and prediction of patients who have a high likelihood of developing chronic pain, a study of patients who were administered a standard battery psychological assessment test found that there is a psychosocial disability variable that is associated with those injured

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	discussion about the standards for judging psychological tests, selection criteria for psychological tests to be used for pain, how many tests should be used, the importance of validity assessment, what psychosocial variables have been found to be especially important and other considerations as well. Commenter adds that the ODG document relies on more dated information in the psychology section, and the ACOEM information is newer. Commenter states that although chronic pain is now almost universally accepted as a biopsychosocial condition, there is very little discussion of this in the ODG document. Commenter indicates that while the chronic pain guideline notes that pain has a psychological component in the introduction, and psychological assessments are mentioned in several places as being recommended, the biopsychosocial model is never very well addressed. Commenter indicates that in contrast to the California/ODG document, the ACOEM documents offer much more detail, first of all about the biopsychosocial model in general, and further, about how to assess this. Commenter states that psychological treatments are also often offered for chronic pain. Commenter states that here again, while both documents talk about cognitive behavioral therapy, and biofeedback, in general the ACOEM document offers a greater amount of detail, and in general seems more accurate. Commenter states that lastly, the ACOEM document also addresses other issues not seen in the California/ODG document. Commenter states that for example, the ACOEM document identifies specific conflicts of interest that might arise for psychologists performing psychological evaluations, such as being			workers who are likely to develop chronic disability problems. (Gatchel, 1999) Childhood abuse and other past traumatic events were also found to be predictors of chronic pain patients. (Goldberg, 1999) Another trial found that it appears to be feasible to identify patients with high levels of risk of chronic pain and to subsequently lower the risk for work disability by administering a cognitive-behavioral intervention focusing on psychological aspects of the pain problem. (Linton, 2002) Other studies and reviews support these theories. (Perez, 2001) (Pulliam, 2001) (Severeijns, 2001) (Sommer, 1998) In a large RCT the benefits of improved depression care (antidepressant medications and/or psychotherapy) extended beyond reduced depressive symptoms and included decreased pain as well as improved functional status. (Lin-JAMA, 2003) See "Psychological Tests Commonly Used in the Assessment of Chronic Pain Patients" from the Colorado Division of Workers' Compensation, which

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	employed by the physician who is making the referrals. Commenter states that here again, he thinks that the ACOEM guidelines are superior.			describes and evaluates the following 26 tests: (1) BHI 2nd ed. -Battery for Health Improvement, (2) MBHI - Millon Behavioral Health Inventory [has been superceded by the MBMD following, which should be administered instead], (3) MBMD - Millon Behavioral Medical Diagnostic, (4) PAB - Pain Assessment Battery, (5) MCMI-111 - Millon Clinical Multiaxial Inventory, (6) MMPI-2 - Minnesota Inventory, (7) PAI - Personality Assessment Inventory, (8) BBHI 2 - Brief Battery for Health Improvement, (9) MPI - Multidimensional Pain Inventory, (10) P-3 - Pain Patient Profile, (11) Pain Presentation Inventory, (12) PRIME-MD - Primary Care Evaluation for Mental Disorders, (13) PHQ - Patient Health Questionnaire, (14) SF 36, (15) SIP - Sickness Impact Profile, (16) BSI - Brief Symptom Inventory, (17) BSI 18 - Brief Symptom Inventory, (18) SCL-90 - Symptom Checklist, (19) BDI–II - Beck Depression Inventory, (20) CES-D - Center for Epidemiological

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Studies Depression Scale, (21) PDS - Post Traumatic Stress Diagnostic Scale, (22) Zung Depression Inventory, (23) MPQ - McGill Pain Questionnaire, (24) MPQ-SF - McGill Pain Questionnaire Short Form, (25) Oswestry Disability Questionnaire, (26) Visual Analogue Pain Scale – VAS. (Bruns, 2001) ~~See also Comorbid psychiatric disorders~~." See also. **Biopsychosocial model of chronic pain** See Chronic pain programs (functional restoration programs), which are recommended where there is access to programs with proven successful outcomes, for patients with conditions that put them at risk of delayed recovery, including the detailed "Criteria for use of multidisciplinary pain management programs" highlighted in blue. These treatment programs are based on the biopsychosocial model, one that views pain and disability in terms of the interaction between physiological, psychological

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				and social factors.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Psychological evaluations***	Commenter states that the draft of the guidelines in the ***psychological assessments*** section incorporates listings of common psychological assessments (ages 64-65) from the Colorado Division of Workers Compensation from 2002 which includes the Millon Behavioral Health Inventory (MBHI) and the Millon Behavioral Medical Diagnostic (MBMD) tests. Commenter states that unfortunately, as was noted in the 2002 Colorado document, the MBMD replaced the archaic MBHI test. Commenter adds that by simply listing the MBHI in the chronic pain guidelines, without the attached information supplied in the original documents, this seems to overstate the value of this test. Commenter adds that it is an ethical violation for a psychologist to use a psychological test that is far out of date, when a newer and improved model is available. Commenter sets forth from the APA the following language: " 9.08 Obsolete Tests and Outdated Test Results (a) Psychologists do not base their assessment or intervention decisions or recommendations on data or test results that are outdated for the current purpose. (b) Psychologists do not base such decisions or recommendations on tests and measures that are obsolete and not useful for the current purpose."	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part.** See response to comment submitted by Daniel Bruns, PsyD, Licensed Psychologist, dated July 18, 2008, on the issue of Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Psychological evaluations, above.	See action taken in connection with comment submitted by Daniel Bruns, PsyD, Licensed Psychologist, dated July 18, 2008, on the issue of Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Psychological evaluations***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Psychological***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Psychological evaluations, testing and treatment***. Commenter states that the guideline is ¾ of a page, and includes a listing without discussion in a paragraph of various tests. Commenter adds that the ACOEM Chronic Pain Update recommends ***Psychological evaluations, testing and treatment***.	James E. Lessenger, M.D. August 4, 2008	**Disagree** with the comment as it does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guidelines on the individual treatment topic of	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
evaluations	Commenter observes that the guideline contains 6 pages of recommendations and discussion. Commenter also states that the guidelines have a 40+ page appendix that includes a comprehensive list and discussion of each test.		"psychological evaluations" is not clear as it does not address the substance of the guideline.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Psychological evaluations***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Psychological evaluations, IDDS & SCS (intrathecal drug delivery systems & spinal cord stimulators)***	Commenter references this guideline. Commenter appears to agree with DWC's guideline.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree.**	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Psychological Treatment***	Commenter would maintain the current language in this guideline, (except the references) but recommends including a statement about the prime indication for the treatment is that of addressing the pain. Commenter believes that payors are going to be concerned that DWC is mandating that any psyche issue is going to be part of the therapy.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part. Agree** with commenter's desire to maintain the current language in the guideline. **Disagree** with remaining of the comment for the reasons set forth in the response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Part 2, Pain Intervention and Treatments, Actiq®, above. Moreover, **disagree** with commenter's request that the guideline include "a statement about the prime indication for the treatment is that of addressing the pain" because "payors are going to be concerned that DWC is mandating that any psyche issue is going to be part of the therapy." Commenter appears to be confusing two issues. The determination of whether or not there is a psychological injury is an issue to be determined by a workers' compensation administrative law judge on the basis of whether or not the injury arose out of and in the course of employment. For this determination a psychiatric claim must be filed. However, time limited psychological treatment is core to pain management and if it is for pain, a psychiatric claim does not need to be filed. Psychological treatment for pain does not change how a determination of industrial injury is made under the Labor Code.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Pulsed radiofrequency treatment (PRF)			Intervention and Treatments, Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Pycnogenol (maritime pine bark) [DWC]***	Commenter references the "Pycnogenol (maritime pine bark) [DWC]" guideline which provides as follows: "Pycnogenol (maritime pine bark) is not recommended for chronic pain." Commenter makes reference to his previous notes on the non medical treatments. Commenter suggests that this may be a good place for the MTUS to address the "non-medical treatment" drugs for food drugs and comment about the regulations to cover these items. Commenter stresses that this is an area of great controversy with clients and this is felt to be non-medical and therefore not consistent with the provision for "medical treatment" in the Labor Code.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part. Disagree** with commenter's suggested edits for the reasons set forth in the response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. **Agree** that the chronic pain medical treatment guidelines should address the "medical foods" issue. Commenter has previously raised this issue. See response to comment submitted by same commenter on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Nonprescription medications, above.	See action taken in connection with comment submitted by Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Nonprescription medications, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Rapid detox***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Return to work***. He observes that only 9 lines are used to discuss	James E. Lessenger, M.D. August 4, 2008	**Disagree** with the comment as it does not address the substance of the proposed regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines Part 2. Pain Intervention and Treatments ***Return to work***	return to work. Commenter adds that the ACOEM Chronic Pain Update also recommends ***Return to work*** but offers three (3) pages of discussion on the matter.		Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guidelines on the individual treatment topic of "return to work" is not clear as it does not address the substance of the guideline.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Salicylate topicals [DWC]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended." Commenter requests that in addition to addressing non-medical treatment, a statement in the MTUS about necessity of providing over the counter medication and treatment would be of benefit to the UR organizations.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. **Agree** that the chronic pain medical treatment guidelines should address the "medical foods" issue. Commenter has previously raised this issue. See response to comment submitted by same commenter on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Nonprescription medications,*** above. **Disagree** that these guidelines should address the "necessity of providing over the counter medication and treatment." Over the counter medications and treatment is a coverage issue which is best addressed by fee schedules regulations, not medical treatment guidelines regulations.	See action taken in connection with comment submitted by Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Nonprescription medications***, above.
9792.24.2(a) Chronic Pain	Commenter references the ***SNRIs (serotonin noradrenaline reuptake inhibitors)*** treatment	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggestion to remove the brand	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***SNRIs (serotonin noradrenaline reuptake inhibitors)***	guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: 'See Antidepressants for neuropathic pain. See also venlafaxine ~~(Effexor)~~, desmethylvenlafaxine and duloxetine ~~(Cymbalta)~~."		name of the drug. DWC **agrees** with ODG's practice that while major listings use generic names, ODG also includes brand names for usability. Moreover, **disagree** with the remaining recommended changes as the general editing comments are inconsistent with ODG's style and do not address the substance of the regulations. It is noted that "Desmethylvenlafaxine" is a new drug that ODG has apparently not yet researched to include in the guidelines.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Spinal cord stimulators (SCS)***	Commenter is a leading manufacturer of spinal cord stimulation systems, a therapeutic device that is used for treatment of chronic pain, which can arise after nerve or nervous system injury. Commenter states that spinal cord stimulation is a minimally invasive, non-destructive therapy that is reversible. Commenter states that the U.S. Food and Drug Administration (FDA) recognizes spinal cord stimulation as an aid in the management of chronic intractable pain of the trunk or limbs. Commenter also states that spinal cord stimulation is a covered benefit under Medicare and other governmental health care programs, all major commercial health plans, and most Workers' Compensation programs in the United States. Commenter opines that the updated ACOEM draft Chronic Pain chapter (2008 draft) undertakes a draconian approach to a wide array of proven tests, therapies and interventions used to treat injured workers suffering from pain-related injuries. Commenter also indicates that it is his organization's understanding in discussions with leading	Advanced Neuromodulation Systems Barbara E. Raley, Senior Manager Strategic Health Policy and Reimbursement, August 12, 2008	**Agree in part. Agree** with the comment that the use of spinal cord stimulators (SCS) as recommended by the ODG Guidelines is appropriate in the treatment of chronic pain. In choosing the guidelines, MEEAC reviewed SCS in detail. It is important to note that MEEAC is a balanced committee composed of primary care and specialists, including pain specialists knowledgeable regarding the scientific evidence-base concerning SCS.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	interventional pain professional medical societies that ACOEM's process failed to include experts in many of the areas they evaluated – a process that in the majority of tests, therapies and interventions evaluated in these guidelines yielded recommendations based primarily on the views of ACOEM's extremely limited author panel.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Spinal cord stimulators (SCS)***	Commenter makes reference to the ***Spinal cord stimulators (SCS)*** treatment guideline in the DWC Chronic Pain Medical Treatment Guideline. Commenter states that spinal cord stimulation efficacy differs across time in all quality studies with at least one year of follow-up. Commenter states that this is a potentially major and limiting aspect of this therapy, beyond the paralysis and other adverse complications. Commenter adds that major complications of interventions have to be discussed to give a balanced view of the condition. Commenter indicates that the implications that spinal cord stimulation is not effective at 3 years (Kemler) must be highlighted and that limitation along with complications discussed so that patients are adequately prepared for the risks and benefits of the procedure. (DWC Chronic Pain Medical Treatment Guideline, page 68.)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** Commenter indicates that the implications that spinal cord stimulation is not effective at 3 years must be highlighted and that limitation along with complications discussed so that patients are adequately prepared for the risks and benefits of the procedure. In light of the comment, ODG has conducted an evidence-based review. In their updated guideline, ODG cites, a recently published 5-year data from a study showing that change in pain intensity was not significantly different between the Spinal Cord Stimulation plus Physical Therapy group and the Physical Therapy alone group. (Kemler, 2008). Thus, commenter is incorrect in its assertion that the guideline should highlight that spinal cord stimulation is not effective at 3 years.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	Commenter makes reference to proposed section 9792.24.2(d), which states that "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline shall apply." Commenter agrees with the intent of the proposed	Jeffrey S. Harris, M.D. August 11, 2008	**Agree in part. Agree** that proposed section 9792.24.2(d) is intended to avoid internal conflict in the MTUS, "[w]hen the treatment is addressed in both the chronic pain medical treatment guidelines and the specific	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Spinal cord stimulators (SCS)	regulations to address conflict with body part chapters in the MTUS by deferring to the relevant body part chapter to avoid contradictory advice. Commenter opines that this is an excellent concept and should avoid confusion and disputes. Commenter opines that this should be applied to spinal cord stimulators (SCS) (p. 67), by deleting this topic from the chronic pain medical treatment guidelines.		guideline found in the clinical topics section of the MTUS, the chronic pain medical treatment guideline" applies. **Disagree** with the suggestion to remove the individual topic guideline of "spinal cord stimulators (SCS)" from the chronic pain medical treatment guidelines. After the condition has been determined to be chronic and the injured worker is receiving treatment under the chronic pain medical treatment guidelines, it is appropriate for that injured worker to continue to receive treatment under that guideline, including "spinal cord stimulators (SCS)" which are available under the chronic pain guidelines. This avoids internal conflict in the MTUS and ensures provision of continuous effective medical treatment without interruption.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Spinal cord stimulators (SCS)***	With regard to recommendations for Spinal Cord Stimulators, commenter states that many of the studies of spinal cord stimulators were too short to assess long term effectiveness or complications. Commenter states that the two studies (Kumar et al) purported to be controlled trials were long enough but were in fact case series, not controlled trials. Commenter states that one also featured post-hoc subgroup analysis, which negates Intention to Treat analysis, a cornerstone of proper RCT design. Commenter also reiterates that recommendations apply to some low back conditions, creating conflicts with other MTUS guidelines. Commenter also notes	Jeffrey S. Harris, M.D., August 11, 2008	**Disagree**. Commenter refers to the ACP/APS guidelines to support his review of the evidence. The ACP/APS guidelines have not yet been published and therefore DWC is unable to independently verify the contents of those guidelines.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	that the recent ACP/APS low back guidelines, produced by investigators at the University of Oregon and an expert panel, do not recommend spinal cord stimulators, facet blocks, or most other injections.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Spinal cord stimulators (SCS)***	Commenter states that NTAC is a national coalition founded by leading interventional pain physician societies and medical device manufacturers dedicated to promoting appropriate access to implantable neuromodulation therapies, which include spinal cord stimulation (SCS) and intrathecal drug delivery systems (IDDS) used to treat patients with intractable, chronic pain. Commenter states that with respect to ***Spinal cord stimulators (SCS)***, his organization strongly supports the language in the proposed Chronic Pain Medical Treatment Guidelines (pages 67-69 of 83), which closely parallels recommendations found in the Official Disability Guidelines (ODG) published by the Work Loss Data Institute, an evidence-based guideline used in approximately 20 states throughout the country. Commenter adds that this recommendation is consistent with that of virtually all state workers' compensation programs, state Medicaid programs, Medicare and the VA. Commenter also states that SCS is a covered benefit under Medicare and other governmental health care programs, all major commercial health plans, and most Workers' Compensation programs in the U.S. Commenter indicates that the Centers for Medicare and Medicaid Services (CMS) provided national coverage for SCS after determining that the therapy met the agency's stringent requirements for medical necessity. Commenter adds that most major private payers including Aetna, Cigna, United Healthcare, Blue Cross/Blue Shield, and Health Net, have formal coverage policies for SCS. Commenter indicates that the US Military Health System also covers SCS for active and retired military personnel and their	Eric Hauth, Executive Director Neuromodulation Therapy Access Coalition August 12, 2008	**Agree.**	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	families.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Spinal cord stimulators (SCS)***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends ***Spinal cord stimulators***. He observes that it is recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. He indicates that the guidelines use 15 references, which include citations of 2 consensus groups. Commenter adds that the ACOEM Chronic Pain Update also recommends ***Spinal cord stimulators***. He indicates that the discussion in the subject is 3 pages long, that there are 2 recommendations, and that it is recommended in CRPS. He also states that the guidelines include a table with selection criteria. He states that the sources for the recommendations are 2 Random Control Trials, 5 systemic reviews, 2 guidelines, and 9 other studies.	James E. Lessenger, M.D. August 4, 2008	**Disagree** with the comment as it does not address the substance of the proposed regulations. Commenter's comparison between ACOEM's chronic pain guideline and DWC's chronic pain medical treatment guidelines on the individual treatment topic of "spinal cord stimulators (SCS)" is not clear as it does not address the substance of the guideline.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Spinal cord stimulators (SCS)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. Indications for stimulator implantation: • Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation), more helpful for lower extremity than low back pain, although both stand to benefit, 40-60% success rate 5 years after surgery. It works best for neuropathic pain. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	caution in the cervical region than in the thoracic or lumbar. • Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.) • Post amputation pain (phantom limb pain), 68% success rate • Post herpetic neuralgia, 90% success rate • Spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury) • Pain associated with multiple sclerosis • Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Stellate ganglion block***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Recommended as indicated below. For diagnosis and treatment of sympathetic pain involving the face, head, neck, and upper extremities secondary to CRPS-I and II, and shingles." Commenter questions the last sentence of this section which reads: "One to three blocks may be given therapeutically as an adjunct to functional exercise." Commenter questions whether DWC is suggesting that the number of blocks be capped at 3.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part. Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. Moreover, ODG has conducted its own evidence-based review, and has updated the individual treatment guideline on "Stellate ganglion block." The original guideline would appear to limit the number of blocks to three. However, the guideline has been completely revised and it now refers the reader to CRPS, sympathetic and epidural blocks for specific recommendations for	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Stellate ganglion block***, has been revised as follows: **"Stellate ganglion block** "~~Recommended as indicated below. For diagnosis and treatment of sympathetic pain involving the face, head, neck, and upper extremities secondary to CRPS-I and II, and shingles. This block is commonly used for differential diagnosis and is the preferred treatment of~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			treatment. The guideline further indicates that detailed information about stellate ganglion blocks is found in Regional sympathetic blocks. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	~~CRPS I pain involving the upper extremity. For diagnostic testing, one should be sufficient. For a positive response, pain relief should be 50% or greater for the duration of the local anesthetic and pain relief should be associated with functional improvement. One to three blocks may be given therapeutically as an adjunct to functional exercise. (Colorado, 2002) (Price, 1998)~~ "Recommendations are generally limited to diagnosis and therapy for CRPS. See CRPS, sympathetic and epidural blocks for specific recommendations for treatment. Detailed information about stellate ganglion blocks, thoracic sympathetic blocks, and lumbar sympathetic blocks is found in Regional sympathetic blocks."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Substance abuse***	Commenter references ***Substance abuse (tolerance, dependence, addiction)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "DSM-IV Criteria for substance abuse	Robert L. Barkin, PharmD, M.B.A.	**Agree in part**. After reviewing the evidence-based, ODG has accepted commenter's edits and has amended the subtitles in its guideline of substance-abuse to reflect commenter's recommended suggested term "cautionary" because the addition of	The Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Substance abuse (tolerance, dependence, addiction) individual treatment topic guideline is amended at page 112, last

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
(tolerance, dependence, addiction)	1) Failure to fulfill major role obligations at work, school or home, 2) Recurrent substance abuse in situations in which it is physically hazardous, 3) Recurrent legal problems associated with substance abuse, 4) Continued use despite persistent or recurrent social or interpersonal problems related to use. Cautionary ~~Red~~ flags for patients that may potentially abuse opioids: (a) History of alcohol or substance abuse, (b) Active alcohol or substance abuse, (c) Borderline personality disorder, (d) Mood disorders (depression) or psychotic disorders, (e) Non-return to work for >6 months, (f) Poor response to opioids in the past. (Washington, 2002) Cautionary ~~Red~~ flags of addiction:"		"cautionary" means that additional clinical judgment may be necessary. DWC **agrees** with commenter's and ODG's edits and is adopting the suggested edit into its adapted version of the guidelines However, the commenter suggested that the word "red" be deleted in its entirety. Both ODG and DWC **disagreed** with the revised language as the term "red flag" has an established meaning. An early use of the Red Flag concept came from the original Agency for Healthcare Research and Quality (AHCPR) guidelines and the meaning of this term has not changed from the original intention, i.e., a Red Flag is a clinical sign, symptom, suspicion, or indicator that there is a potentially serious condition.	two paragraph, as follows: **"Cautionary ~~R~~red flags for patients that may potentially abuse opioids:** (a) History of alcohol or substance abuse, (b) Active alcohol or substance abuse, (c) Borderline personality disorder, (d) Mood disorders (depression) or psychotic disorders, (e) Non-return to work for >6 months, (f) Poor response to opioids in the past (Washington, 2002) **"Cautionary ~~R~~red flags of addiction:** 1) Adverse consequences: (a) Decreased functioning, (b) Observed intoxication, (c) Negative affective state 2) Impaired control over medication use: (a) Failure to bring in unused medications, (b) Dose escalation without approval of the prescribing doctor, (c) Requests for early prescription refills, (d) Reports of lost or stolen prescriptions, (e) Unscheduled clinic appointments in "distress", (f) Frequent visits to the ED, (g) Family reports of overuse

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				or intoxication 3) Craving and preoccupation: (a) Non-compliance with other treatment modalities, (b) Failure to keep appointments, (c) No interest in rehabilitation, only in symptom control, (d) No relief of pain or improved function with opioid therapy, (e) Medications are provided by multiple providers. (Wisconsin, 2004)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Sympathetic therapy [ODG]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Testosterone replacement for hypogonadism (related to opioids) [DWC]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long term high dose opioids. Routine testing of testosterone levels in men taking opioids is not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain	Commenter references the Topical analgesics treatment guideline, and questions whether the	Philipp M. Lippe, M.D.	**Agree.** Although the individual treatment guideline topic for	Section 9792.24.2(a), Chronic Pain Medical

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical analgesics***	guideline distinguishes between topical analgesics and transdermal analgesics?	Medical Corporation, Consultant August 11, 2008	"Topical analgesics," contains language that state "[t]hese agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate," ODG has conducted its own evidence-based review, and has updated its individual treatment guideline topic for "Topical analgesics." Specifically, the guideline has been updated to include a note which states "[t]opical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic® (fentanyl transdermal system)." This revised portion of the guideline, as contained in the October 23, 2008 version of ODG's revised guidelines, addresses commenter's concern by indicating that topical analgesics do not include transdermal analgesics. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. The entire updated guideline is set forth in the action column of this chart for the benefit of the regulated public.	Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Topical analgesics*** has been revised as follows: **"Topical Analgesics** "Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic® (fentanyl transdermal system).] **"*Non-steroidal antinflammatory agents (NSAIDs):*** The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) *Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment:* Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. *Neuropathic pain:* Not recommended as there is no evidence to support use. *FDA-approved agents: Voltaren® Gel 1% (diclofenac)*: Indicated for relief of osteoarthritis pain in joints that lend themselves to

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren® package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. *Non FDA-approved agents: Ketoprofen:* This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel, 2000)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				"Lidocaine *Indication: Neuropathic pain* Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). ~~This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia.~~ Topical lidocaine, in the formulation of a dermal patch (Lidoderm®) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-*Cochrane*, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) *Non-neuropathic pain:* Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995) ***"Capsaicin:*** Recommended only as an option in patients who have not responded or are intolerant to other treatments. *Formulations:* Capsaicin is generally available as a 0.025% formulation (as a treatment

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. *Indications:* There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-*BMJ*, 2004) See also **Capsaicin**.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				"~~Other agents: Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post herpetic neuralgia, and both studies showed encouraging results. Topical clonidine has published reports in animal studies only. Topical gabapentin has no published reports.~~ ***"Baclofen:*** Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. ***"Gabapentin:*** Not recommended. There is no peer-reviewed literature to support use. ***"Ketamine:*** Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also **Glucosamine (and Chondroitin Sulfate)**; & **Topical analgesics, compounded**. "~~Non-neuropathic pain (soft tissue injury and osteoarthritis).~~ "~~NSAIDS: The efficacy in clinical trials for this treatment modality have been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Ketoprofen is under study in a patch formulation for treatment of ankle strain and for tendonitis/bursitis of the elbow, shoulder and knee in phase II clinical trials in Europe.~~ "~~Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. See also Capsaicin.~~ "~~Lidocaine: There are no randomized controlled trials evaluating the use of topical lidocaine for treatment of low back pain or osteoarthritis, and treatment with this modality is not currently recommended.~~ "~~Other agents: Topical glucosamine, chondroitin and camphor showed significant pain relief for~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~osteoarthritis of the knee after 8 weeks compared to placebo. (Cohen, 2003) See also Glucosamine (and Chondroitin Sulfate). For non-neuropathic low back and myofascial pain there are few published studies. (Argoff, 2006)~~"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical Analgesic***	Commenter references this guideline, which states as highlighted by commenter in pertinent part, "Recommended as an option as indicated below;" "There is little to no research to support the use of many of these agents;"and "The use of these compounded agents …." Commenter opines that this will be difficult to control and involves the compounding and office dispensing which has become an acrimonious issue. Commenter opines that since the literature support is minimal at best, DWC should think about disallowing it altogether.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. Moreover, **disagree** with commenter's recommendation that DWC think of disallowing "topical analgesics" altogether because "the literature research is minimal at best," and it will be difficult to control as this involves "the compounding and office dispensing which has become an acrimonious issue." The individual treatment guideline topic for "Topical analgesics," recommends the use of topical analgesics as the use of the topical analgesics is supported by evidence-based medicine. The guideline indicates that use is "[p]rimarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed.	See action taken in connection with the comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Topical Analgesic.***

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			(Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006)" The guideline goes on to explain which topical analgesics are not recommendated as not supported by the evidence-base. Commenter appears to confuse the issues of medical treatment guidelines vs. costs. The MTUS regulations are not the proper vehicle to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to "assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and … constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions." Lab. Code, 4604.5(b). Nevertheless, for the reasons set forth above in the response to the comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on the individual treatment guideline topic of "Topical analgesics," the guideline has been revised.	
9792.24.2(a) Chronic Pain	Commenter references ***Topical Analgesics*** treatment guideline contained in Part 2. Pain Intervention and	Robert L. Barkin, PharmD, M.B.A.	**Agree in part. Agree** with commenter's reference that	See action taken in connection with the

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical Analgesics***	Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: "Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, <u>diclofenac,</u> opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. <u>Diclofonac (gel and patch) are FDA approved dosage forms.</u>" Commenter further edits the guideline as follows: NSAIDS: The efficacy in clinical trials for this treatment modality have been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004)		"diclofenac" is an approved FDA topical analgesic agent. The updated ODG version dated October 23, 2008, as adapted by DWC, contains this revised information as follows: "*FDA-approved agents: Voltaren® Gel 1% (diclofenac)*: Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren® package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function." **Disagree** with commenter's specific edits as inconsistent with ODG's style.	comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Topical Analgesic.***

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Ketoprofen is under study in a patch formulation for treatment of ankle strain and for tendonitis/bursitis of the elbow, shoulder and knee in phase II clinical trials in Europe. Diclofonac (gel and patch) are FDA approved dosage forms.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical analgesics – Compounded [DWC]***	Commenter raises his concern regarding the "Not recommended" recommendation in the ***Topical analgesics – Compounded [DWC]***. Commenter believes the format in which the content for the guidelines are presented will be misinterpreted by the industry as a whole, specifically as it relates to topical compounds. Commenter indicates that he appreciates the fact that the guideline is created to help control costs associated with the practice of medicine in the workers' compensation arena, however, to control costs while limiting patient access, or to control costs while prohibiting the practice of medicine is disingenuous, in commenter's opinion, and most likely unconstitutional. Commenter states that as a pharmacist and former adjunct professor at USC School of Pharmacy teaching pharmaceutical compounding, he believes it is short sighted for the DWC to unilaterally declare "Topical Compounds" as not recommended. Commenter indicates that there are over 1000 various combinations of topical compounds in use across the	Robert Nickell, Pharmacist Nickell Group Pharmacy Services August 10, 2008	**Disagree.** See response to comment contained in Memorandum to the Rulemaking File, dated November 26, 2008, which addresses the individual treatment guideline on "Topical analgesics – Compounded [DWC]." The November 26, 2008 Memorandum to the Rulemaking file is adopted and incorporated as part of this rulemaking chart, and specifically addresses commenter's comment. It is noted that in his comment, Commenter alleged that "the evidence-based search process was not complete." Commenter argued that the evidence-based search should have been conducted "for individual active ingredients used topically, or transdermally." Commenter further alleged that a search conducted in this manner "would discover hundreds of articles that would fit	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Topical analgesics – Compounded [DWC]***, has been revised as follows: **"Topical Analgesics, – ~~C~~compounded ~~[DWC]~~** "Not recommended. There is ~~no~~ mixed evidence ~~that~~ about whether compounding topical medications, such as adding an anti-inflammatory agent to capsaicin, is more efficacious than the single medication. Furthermore, ~~the~~ a recent FDA ~~has issued warnings~~ warning ~~on~~ about the potential dangers of compounding topical

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	USA. Commenter indicates that compounded medications are used by every practice specialty, every type of disease state and type of patient. Commenter states that compounds are utilized daily in hospitals, hospice, medical groups, private physician practice, independent pharmacies, chain pharmacies, and other types of clinics across the country. Commenter indicates that there is so much more to topical compounding than the paragraph declaring the category "not recommended." Commenter further indicates that the evidenced based search process was not complete in his opinion. Commenter opines that searching for topical compounds for pain is not going to reveal much to the researcher, however, if they were to search for individual active ingredients used topically, or transdermally, the researcher would discover hundreds of articles that would fit the criteria for EBR. Commenter states that searching beyond active ingredient, combination of active ingredients, strengths, and therapeutic categories will reveal even more. Commenter states that there is at least as many if not more, class C substantiated EBR in favor of various topical compounds as there are for unsubstantiated claims, which in his opinion renders the decision not proving or disproving efficaciousness at this time, in essence, "under study" and thus the decision to prescribe a topical compound should remain with the physician treating the patient with the most tools available without compromise. Commenter adds that throughout the narrative, and after reviewing countless articles as presented in the MTUS, it appears that "off-label" use, and use other than that in which the drug is FDA indicated is acceptable within the DWC. Commenter questions why then would		the criteria for EBR." In response to commenter's allegations, DWC followed up with the commenter and asked him for the specific articles the commenter was referencing. Commenter submitted his articles, which DWC subjected to evidence-based reviews in accordance with the Title 8 Cal. Code Regs. § 9792.22 (now proposed § 9792.25) criteria of the MTUS. Further explanation of this review is contained in the November 26, 2008 Memorandum to the Rulemaking file, which has been adopted and incorporated as part of this rulemaking chart. Moreover, **disagree** with the comment that "the guideline is created to help control costs associated with the practice of medicine in the workers' compensation arena." The MTUS regulations are not the proper vehicle to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to "assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and … constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial	medication containing local anesthetics supersedes any recommendation (U.S. Food and Drug Administration, FDA News, December 5, 2006, FDA Warns Five Firms to Stop Compounding Topical Anesthetic Creams. (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01516.html) The FDA warns, that ~~E~~exposure to high concentrations of local anesthetics, like those in compounded topical anesthetic creams, can cause grave reactions (including seizures, ~~and~~ irregular heartbeats and death). ~~At least two deaths have been connected to compounded topical anesthetic creams. (FDA Advisory 12/05/06)~~ Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	topical compounds simply be negated based on poor research and a warning letter released by the FDA referencing topical lidocaine as used by laser surgery centers for hair removal? Commenter indicates that the choice of medication therapy should be left to the physician as they are deemed competent as the treating physician and the surgeon by the carrier. Commenter further states that compounded pharmaceuticals are the cornerstone of the practice of pharmacy and have been in existence for thousands of years. Commenter adds that compounding is recognized as a legitimate standard of medical care by the FDA, BOP, Board of Medicine, and the DEA. Commenter recommends that compounding not be regulated by a paragraph on a guideline that universally discounts the use of compounded medications as a whole. Commenter recommends that DWC rather establish an OMFS specifically for compounds. Commenter further recommends that a pharmacist be appointed as a member of the EBR committee, as most of the articles to be reviewed involve medication, or medication therapy in some form or another.		conditions." Lab. Code, § 4604.5(b). Further, **disagree** with the comment "that the choice of medication therapy should be left to the physician as they are deemed competent as the treating physician and the surgeon by the carrier." The MTUS is presumptively correct (Lab. Code, § 4604.5(c)) and is required to provided evidence-based treatment guidelines (Lab. Code, § 5307.27). Therefore, it cannot be left up to the physician or surgeon. Rather, through the utilization review process, the physicians request treatment, and those requests are reviewed according to the MTUS. Although compounding pharmacy practice has been around for thousands of years, the dispensing of drugs requires a physician's orders, and physicians are required to comply with the MTUS. To the extent that a compounding pharmacist receives a physician order, there is nothing to preclude the compounding pharmacist to carry out the physician orders. Regardless of whether it is a compounded agent versus a commercial agent, utilization review applies to all treatment and does not single out compounded agents. Nevertheless, ODG has conducted its own evidence-based review,	2006) There is little to no research to support the use of many [of] these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required."

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			and has written its own individual treatment guideline on "Topical analgesics – Compounded." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical analgesics – Compounded [DWC]***	Commenter makes reference to a paper attached to his comments, which he has submitted for DWC's review. The paper is entitled "*Topical and Transdermal Therapy for Chronic Pain*," and contains a list of 35 references at the end of the paper. Commenter states that it is appropriate for clinicians to speak to the efficacy and clinical utility of compounded transdermal pain products, and hopes that DWC review the references attached with over thirty published articles on the topic. Commenter states that there is an important detail related to this issue that he was unable to address while at the podium [at the public hearing], clearly important to DWC, particularly [related to] the variability of the price of the compounded prescription items. Commenter quickly acknowledges the cost benefit issue when he learned that some of his competitors charge two to three times what he does for these medications, an egregious practice in his opinion. Commenter states that this is obviously; this is indeed a matter of great concern. Commenter states that surely, products that provide significant benefit to patients may be excluded from use due to price gouging, a practice he is adamantly opposed to. That said, commenter indicates that if the CA DWC is interested in forming a committee or at least interested in his personal analysis of the situation, particularly pricing, he is happy to volunteer his consultative services. Commenter indicates that he would work with a select group of practitioners to develop	Robert Seik, PharmD, MBA President, Partell Specialty Pharmacy Written & Oral August 12, 2008	**Disagree.** See response to comment submitted by Robert Nickell, Pharmacist, Nickell Group Pharmacy Services, dated August 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Topical analgesics – Compounded [DWC], above.	See action taken in connection with comment submitted by Robert Nickell, Pharmacist, Nickell Group Pharmacy Services, dated August 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Topical analgesics – Compounded [DWC], above.

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	guidelines, particularly reimbursement/payment parameters, and provide this information to the CA DWC for consideration. Commenter further states that if he were a member of the CA DWC and supportive of the use of compounded transdermal products for pain management, he would suggest a pricing schedule that paying carriers/insurers may use to decide on maximum reimbursement. Commenter states that based on the feedback he received at the hearing from attending physicians, and practitioners, patients could continue to benefit from using these products while dramatically reducing the cost-burden that may be associated with outrageous pricing schedules charged by some compounding pharmacies.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical analgesics – Compounded [DWC]***	Commenter submits his formal professional objection on behalf of his organization to the DWC's MTUS proposal to effectively abolish the usage of compounded topical medication. Commenter states that as a full time PM&R physician, the majority of his practice consists of the management of both acute and chronic work related injuries. Commenter indicates that he has innumerable examples of cases in his practice in which the use of compounded medications, those NOT available via commercial pharmacies, has resulted in symptomatic and functional improvement for injured workers. Commenter states that the use of topical treatments, although well established in compounded form for soft tissue injuries, is rather novel in the world of "evidence based medicine" as it relates to the commercial pharmaceutical industry. Commenter indicates that this is evidenced by the paucity of commercial products approved by the FDA for the topical management of pain conditions. Commenter indicates that said, they are limited as practitioners to only a couple of active ingredients, doses, and delivery vehicles. Commenter states the use of	Jeffrey D. Scott, M.D. Board Certified Physical Medicine and Rehabilitation Northern California Rehabilitation Associates August 11, 2008 Tom Waldorf August 12, 2008 Oral Comment	**Disagree.** See response to comment submitted by Robert Nickell, Pharmacist, Nickell Group Pharmacy Services, dated August 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Topical analgesics – Compounded [DWC], above.	See action taken in connection with comment submitted by Robert Seik, PharmD, MBA, President, Partell Specialty Pharmacy, dated August 12, 2008, on the issue of Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Topical analgesics – Compounded [DWC]***, above.

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	compounded medications has allowed them as the providers to expand the concept of topical treatment for pain to include more conditions and a much larger patient base. Commenter offers as an example, the Flector patch, which according to the commenter has recently been approved for "acute short pain due to minor sprain, strains." Commenter states that with the active ingredient, non-steroidal diclofenac, the Flector patch is sometimes not tolerated by the patient because it is not strong enough, has a delivery method (patch) that is too irritating for the patient, or the patch does not adhere properly. Commenter indicates that the use of topical indocin, another non-steroidal which is not available commercially, allows him to hand pick the dose, change dosing intervals, and provide the patient with a different delivery method (cream base). Commenter states that another example is the Lidoderm patch, which is FDA approved for the use of certain nerve conditions. Commenter indicates that again this is available in only a 5% dose and a single delivery method. Commenter indicates that he will not be able to treat his burn patient who has such severe nerve pain in his feet he cannot wear socks or shoes much less the patches. Commenter adds that the patient has only been able to continue gainful employment with use of compounded 10% lidocaine cream applied twice daily under his socks and steel toed shoes. Commenter states that it is clear by this proposal that the medical literature supporting compounding is being ignored. Commenter states that double blinded control clinical trials are expensive. Commenter states that pharmaceutical companies will not pay for further studies since they cannot patent compounds and			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	receive any financial gain. Commenter wonders how ironic it is that opioids are freely endorsed and prescribed in sometimes escalating doses despite the lack of well designed controlled trials supporting functional improvement. Commenter indicates that opiate side effects: dependency, hormonal imbalance, and addiction are known complications and encountered on a daily basis. Commenter states they have yet to encounter such an issue with compounded topical medication. Commenter offers that if this narrow minded decision is passed by the DWC, it is yet another example of cost savings at the expense of reasonable medical care meant "to cure and/or relieve" the effects of an injury. Commenter states that it is also confirmation to the medical community and the public of how out of touch the department is with the medical providers who are actually caring for injured workers in the state of California.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical analgesics – Compounded [DWC]***	Commenter states that she applauds the discussion of topicals addressed in the MTUS, and the specific recommendation against compounded topicals. Commenter states that she brought the issue of compounded formularies to the attention of the DWC back in November of 2007. Commenter states that since then, Contra Costa County has seen several more physicians (not just the Dr. "X" referred to in my original email) prescribing/dispensing compounded formularies. Commenter indicates that the recently-enacted Pharmaceutical Fee Schedule has effectively eliminated the majority of the prescription abuse and waste previously seen in workers' compensation (capping prices for repackaged meds). Commenter indicates that the Pharmaceutical Fee Schedule was a solution the industry she represents desperately needed because the cost of repackaged medications dispensed by occupational	Denise Niber-Montoya Sr. Claims Adjuster Contra Costa County Risk Management August 12, 2008	**Agree in part. Agree** that it is important to address the individual treatment guideline topic of "Topical analgesics – Compounded" in the chronic pain medical treatment guidelines. **Disagree** that the MTUS regulations are the proper vehicle to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to "assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and … constitute care in accordance	See action taken in connection with comment submitted by Robert Nickell, Pharmacist, Nickell Group Pharmacy Services, dated August 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Topical analgesics – Compounded [DWC]***, above.

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	treaters had historically been approximately 80% more than the cost of those same drugs when filled at pharmacies (California Commission on Health and Safety and Workers Compensation, July 2006, "Impact of Physician-Dispensing on Repackaged Drugs…"). Commenter states than soon after the enactment of the Pharmaceutical Fee Schedule, however, she started seeing physicians dispense compounded creams and capsules. Commenter adds that since these compounded formularies fall outside the OMFS, they are billed at prices far-exceeding those for therapeutic equivalents already on the market, in either over-the-counter, or prescription form. Commenter indicates that she recognizes the benefit, necessity and legality of compounding as a part of the pharmacist's role, based on the specific needs of particular patients. However, not all patients (and certainly not a "class of patient" -- in this case injured workers) require compounded formularies. Commenter indicates that her concern is that while each ingredient may be FDA recognized, the FDA has not sanctioned, condoned, or "approved" the mass production of compounded medications. Commenter adds that it is believed that this practice runs counter to the intent of SB 899, LC 4600 and the recent amendment to the OMFS, Section 9789.40, concerning repackaged drugs. Commenter states that regarding topicals, her industry finds it unreasonable to have to pay hundreds of dollars (approx. $270.00) for a compounded cream, whose active ingredient(s) can be found in already-available over-the-counter or prescription products (ones regulated and approved by the FDA), at a fraction of that price. Commenter states that for example, Wasabi ™ contains capsaicin as its active ingredient; yet, capsaicin cream is already available on the market, with a generic price of approx. $13.02 (.25% capsaicin, 60 gm). Commenter adds that likewise, there are commercially-available,		with Section 4600 for all injured workers diagnosed with industrial conditions." Lab. Code, 4604.5(b). Moreover, it is noted that commenter does not provide any scientific evidence in support of the issues she raises, which would justify a substantive modification to the regulations, and specifically to the individual treatment guideline topic of "Topical analgesics – Compounded."	

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	FDA-approved topical NSAIDs. Commenter indicates that as to the appropriate use and efficacy of topicals in general, the ODG and ACOEM guides address those issues far better than she can. Commenter states that she noted that one of the speakers at the public hearing (a compounding pharmacist) indicated that compounding pharmacies are "small companies" that "cannot afford" to do the expensive testing required: clinical trials, such as double-blinded studies, etc... Commenter states that she has investigated the source for many of the compounded creams for which her industry has been billed, and that source is a compounding lab out of Southern California which generated 6.3M in revenue in 2006 (not a "small" pharmacy). Commenter states that the FDA, likewise, has addressed the issue of compounding labs mass-manufacturing compounded formularies. Commenter questions why do these compounding labs (pharmacist-owned facilities) mass-produce and mass-market to occupational treaters? She suggests the answer is because it is profitable-- profitable for them, the occupational treaters to whom they market, and profitable for the medical "billing services" who often match occupational treaters with their source for these (incredibly expensive) compounded formularies. Commenter shares an article she found on the internet, written by Pharmacist Bruce A. Bouts, RPh, MD, FACP, entitled "The Misuse of Compounding by Pharmacists." (http://www.quackwatch.org/01QuackeryRelatedTopics/compounding.html) Commenter attaches previous abridged letter on the same subject to the DWC, dated 11/1/07.			
Chronic Pain	Commenter makes reference to comments set forth in	Theodore Blatt, M.D.	**Disagree.** Commenter references	See action taken in

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Topical Analgesics-Compounded [DWC]***	Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Topical Analgesic,*** above.	Medical Director , Anthem Blue Cross, July 28, 2008	the same comments he made in connection with the individual treatment guideline topic of "Topical Analgesics." Commenter does not appear to understand that the individual treatment guideline topic of "Topical Analgesics-Compounded [DWC]" is a different guideline. Insofar as commenter is addressing issue related to costs, see response to his comment submitted in connection with the individual treatment guideline topic of "Topical Analgesics," above.	connection with comment submitted by Robert Seik, PharmD, MBA, President, Partell Specialty Pharmacy, dated August 12, 2008, on the issue of Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Topical analgesics – Compounded [DWC]***, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Transcutaneous Electrotherapy [DWC]***	Commenter states that in addition to his organization's request to adopt the current ODG guidelines, their membership has a comment on one section of the electrotherapy draft guidelines: • Physicians are looking for effective non-pharmacologic, non-invasive options to treat the complex subject of pain management. • Electrical stimulation is one of several viable options that a physician may find to be an appropriate treatment for pain. This is a well-accepted clinical treatment modality for pain. • With the legislative mandate limiting physical therapy visits the chronic pain patient doesn't have access to clinical physical therapy. • Therefore there is a legitimate need for home therapies which often include prescribed electrical stimulation in the treatment of injured workers in the California Workers' Compensation system.	Robert R. Thauer, President Alliance for Physical Therapy, Rehabilitation & Medical Technology August 8, 2008 August 11, 2008 Written and Oral Comments	**Agree in part.** Commenter requests that DWC adopt ODG's most current guidelines. DWC **agrees.** DWC proposes to adapt ODG's updated version dated October 23, 2008 in the chronic pain medical treatment guidelines. DWC notes that the individual treatment guideline heading on "Transcutaneous Electrotherapy [DWC]" is an introduction to the subject "transcutaneous electrotherapy." It was written by DWC as an introduction to the specific sections of different individual electrotherapies grouped under the subject-heading "transcutaneous electrotherapy." The section is intended to group all the different individual electrotherapies together, and it is not meant to be an evidence-base review. Rather, the evidence-base	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Transcutaneous Electrotherapy [DWC]***, is modified, in relevant part, as follows: "**Transcutaneous ~~E~~electrotherapy [DWC]** "Electrotherapy represents the therapeutic use of electricity and is another modality that can be used in the treatment of pain. Transcutaneous electrotherapy is the most common form electrotherapy where electrical stimulation is applied to the surface of the skin. The earliest devices were referred to as TENS

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			reviews apply specifically to individual devices, which are grouped under the introduction. The introduction, in addressing commenter's concerns and for clarification purposes, has been amended to state at the end of the section as follows: "All of the following individual treatment topics are from the ODG guidelines." This addresses commenter's concern that DWC adopt ODG's most recent guidelines. **Disagree** with regard to commenter's remaining comments. The comments do not substantively address the substance of the regulations as they do not specifically address the substance of the individual electrotherapies grouped under the heading, "Trancutaneous Electrotherapy [DWC]."	(transcutaneous electrical nerve stimulation) and are the most commonly used. It should be noted that there is not one fixed electrical specification that is standard for TENS; rather there are several electrical specifications. Other devices (such as H-wave stimulation (devices), Interferential Current Stimulation, Microcurrent electrical stimulation (MENS devices), RS-4i sequential stimulator, Electroceutical Therapy (bioelectric nerve block), Neuromuscular electrical stimulation (NMES devices), Sympathetic therapy, Dynatron STS) have been designed and are distinguished from TENS based on their electrical specifications to be discussed in detail below. The following individual treatment topics are grouped together under the topic heading, "Transcutaneous Electrotherapy [DWC]" and are intended to allow the users of the chronic pain medical treatment guidelines to compare their benefits and to choose amongst the various transcutaneous electrical stimulation

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				devices. All of the following individual treatment topics are from the ODG guidelines."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Transcutaneous Electrotherapy [DWC]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Electrotherapy represents the therapeutic use of electricity and is another modality that can be used in the treatment of pain. Transcutaneous electrotherapy is the most common form electrotherapy where electrical stimulation is applied to the surface of the skin." Commenter further states this section in general is problematic. Commenter believes it is going to be open to interpretation and create a good deal of acrimony. Commenter believes the evidence base for these modalities is poor at best and many feel that this is not medically necessary. Commenter suggests further evaluation of this source to address these treatment modalities, although he supports these being addressed in the MTUS.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. Moreover, it is noted that pursuant to ODG's evidence-based review, as set forth in the individual treatment guidelines listed under the subject heading "Transcutaneous Electrotherapy," the guidelines include the criteria for when electrotherapies can be part of the treatment, and acknowledge the limits of the evidence base. Moreover, **disagree** with the comments that "this section in general is problematic," "open to interpretation," and "create a good deal of acrimony." As previously stated, the introduction "transcutaneous electrotherapy" was written by DWC and is an introduction to the specific sections of different types. The need for the section came about in order to group all the different individual electrotherapies together. It is not an evidence review. Rather the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			evidence reviews apply specifically to individual devices. Therefore, as a general introduction, it is not about a specific device or application. Rather it helps to introduce the reader to the group of devices listed in this section to indicate that they are all in the same category, and despite different device names they are all transcutaneous electrotherapies. The devices tend to distinguish themselves by name and features.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***TENS, post operative pain (transcutaneous electrical nerve stimulation) [ODG]***	Commenter references the first sentence of this guideline, which provides: "Recommended as a treatment option for acute post-operative pain in the first 30 days post-surgery." Commenter questions whether DWC is limiting this to thoracotomy only? Commenter also questions whether this is limited to a 30 day period only?	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree**. TENS as set forth in the individual treatment guideline on "TENS, post operative pain (transcutaneous electrical nerve stimulation)" is limited to thoracotomy pain. The guideline is rather specific as it states that "TENS appears to be most effective for mild to moderate thoracotomy pain," and it qualifies its usage as it states that "[i]t has been shown to be of lesser effect, or not at all for other orthopedic procedures." Moreover, the 30 day limitation is for the immediate post-operative period. Treatment with TENS beyond that would fall outside of this recommendation and other TENS guidelines can be used instead. (See §9792.21(c).) **Disagree** – that TENS is limited to thoracotomy pain, rather it specifically states "TENS appears	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			to be most effective for mild to moderate thoracotomy pain." It further states: "It has been shown to be of lesser effect, or not at all for other orthopedic procedures." The 30 days is for the immediate post operative period. Beyond that would fall outside of this recommendation and other TENS guidelines can be used instead.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Transcutaneous Electrotherapy [DWC]*** ***H-wave stimulation (devices) [ODG]***	Commenter submits research on an H-Wave device for review by the DWC. Commenter states, for clarification purposes, that DWC may have found some studies done by McDowell that reference H-Wave or HWT during its research. Commenter further states that though this is a confusing issue those studies were not done with the FDA cleared and US trademarked H-Wave that his company (Electronic Waveform Lab) manufactures. Commenter indicates that the device they used is not legal in the United States and is completely unrelated to their US H-Wave. The attached studies are entitled: (1) "The H-Wage Small Muscle Fiber Stimulator, a Nonpharmacologic Alternative for the treatment of Chronic Soft-Tissue Injury and Neuropathic Pain: An Extended Population Observational Study"; (2) "The H-Wave Device is an Effective and Safe Non-Pharmacological Analgesic for Chronic Pain: a Meta Analysis"; (3) "Diabetic Peripheral Neuropathy: Amelioration of Pain With Transcutaneous Electrostimulation"; (4) "Diabetic Peripheral Neuropathy: Effectiveness of electrotherapy and amitriptyline for symptomatic relief"; (5) "The microvascular and hemodynamic mechanisms for the therapeutic actions of H-Wave muscle stimulation"; (6) "Post Operative Management of Rotator Cuff	Ryan Heaney, President Electronic Waveform Lab, Inc. August 14, 2008	**Agree in part.** ODG has conducted its own evidence-based review and has updated its individual treatment guideline topic on "H-way stimulation (HWT)." In the revised individual treatment guideline topic on "H-way stimulation (HWT)," ODG has updated the guideline to take into consideration commenter's request for clarification regarding the devices used for H-Wave and HWT. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	Section 9792.24.2(a), Chronic Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Transcutaneous Electrotherapy [DWC], H-wave stimulation (devices) [ODG] has been modified as follows: **"H-wave stimulation (~~devices~~HWT) ~~[ODG]~~** "Not recommended as an isolated intervention, but a one-month home-based trial of H-Wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain (Julka, 1998) (Kumar, 1997) (Kumar, 1998)~~,~~ or chronic soft tissue inflammation if used as an adjunct to a program of evidence-based

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	Reconstruction: Transcutaneous Electro Stimulation"; (7) Beneficial Effects of Electrical Stimulation on Neuropathic Symptoms in Diabetes Patients"; (8) "Electrical Stimulation Reduces Symptoms of Thermal Hypersensitivity from Injury of Sciatic Partial Ligation in Rats"; (9) "H-Wave, a Nonpharmacologic Alternative for the Treatment of Patients With Chronic Soft Tissue Inflammation and Neuropathic Pain: A Preliminary Statistical Outcome Study."			functional restoration, and only following failure of ~~other~~ initially recommended ~~pain modalities~~ conservative care, including recommended physical therapy (i.e., exercise) and medications, plus transcutaneous electrical nerve stimulation (TENS). In a recent retrospective study suggesting effectiveness of the H-wave device, the patient selection criteria included a physician-documented diagnosis of chronic soft-tissue injury or neuropathic pain in an upper or lower extremity or the spine that was unresponsive to conventional therapy, including physical therapy, medications, and TENS. (Blum, 2006) (Blum2, 2006) There is no evidence that H-Wave is more effective ~~than~~ as an initial treatment when compared to TENS for analgesic effects. ~~despite the significantly higher cost of H-Wave, so TENS would be recommended for the treatment of diabetic neuropathy over H-Wave unless documentation can support medical necessity.~~ A randomized controlled trial comparing analgesic effects

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				of H-wave therapy and TENS on pain threshold found that there were no differences between the different modalities or HWT frequencies. (McDowell2, 1999) [Note: This may be a different device than the H-Wave approved for use in the US.] Regarding tissue repair, another study suggests that low-frequency HWT may produce direct localized effects on cutaneous blood flow, a finding relevant for clinicians working in the field of tissue repair. (McDowell, 1999) The one-month HWT trial may be appropriate to permit the physician and provider licensed to provide physical therapy to study the effects and benefits, and it should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) as to how often the unit was used, as well as outcomes in terms of pain relief and function. Rental would be preferred over purchase during this trial. Trial periods of more than one month should be justified by documentation submitted for review. While

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				H-Wave and other similar type devices can be useful for pain management, they are most successfully used as a tool in combination with functional improvement. ~~While H-Wave and other similar type devices can be useful for pain management, they are often over-prescribed and used as a passive intervention rather than as a tool in combination with functional restoration. For diabetic neuropathy unresponsive to more conventional treatment, a one-month trial may be appropriate to permit the physician and physical therapist to study the effects and benefits, and it should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial. Trial periods of more than one month should be justified by documentation submitted for review. Three small controlled trials provide suggestive evidence~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~about the effectiveness of H-wave electrical stimulation for diabetic neuropathy, but evidence is lacking for other conditions. There are no high quality studies demonstrating the effectiveness of H-Wave for conditions other than diabetic neuropathy.~~ H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS), in terms of its waveform. While physiatrists, chiropractors, or podiatrists may perform H-wave stimulation, H-wave devices are also available for home use. H-wave stimulation is sometimes used for the treatment of pain related to a variety of etiologies, muscle sprains, temporomandibular joint dysfunctions or reflex sympathetic dystrophy. In fact, H-wave is used more often for muscle spasm and acute pain as opposed to neuropathy or radicular pain, since there is anecdotal evidence that H-Wave stimulation helps to relax the muscles, but there are no published studies to support this use, so it is not

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				recommended at this time. H-wave stimulation has also been used to accelerate healing of wounds, such as diabetic ulcers. H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography. ~~(Julka, 1998) (Kumar, 1997) (Kumar, 1998) (McDowell, 1999) (McDowell2, 1999) (BlueCross BlueShield, 2005)~~ (BlueCross BlueShield, 2007) (Aetna, 2005) ~~(Blum, 2006) (Blum2, 2006)~~ *Recent studies:* A recent low quality meta-analysis concluded that the findings indicate a moderate to strong effect of the H-Wave device in providing pain relief, reducing the requirement for pain medication and increasing functionality, with the most robust effect observed for improved functionality, suggesting that the H-Wave device may facilitate a quicker return to work and other related daily activities. The low quality rating for this "meta-analysis" is primarily because the numbers were dominated by results from studies that were not

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				prospective randomized controlled trials, but instead were retrospective observational studies using a patient survey, the H-Wave Customer Service Questionnaire, without a prospective control group. More definitive results may be on the way. According to this study, "double-blinded studies of the H-Wave device are currently underway and results will be awaited with interest." (Blum, 2008)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***H-wave stimulation (devices) [ODG]***	Commenter references the portions of the guideline, which provide: "Not recommended as an isolated intervention, but a one-month home-based trial of H-Wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain, if used as an adjunct to a program of evidence-based functional restoration, and only following failure of other recommended pain modalities." "There are no high quality studies demonstrating the effectiveness of H-Wave for conditions other than diabetic neuropathy." Commenter questions whether this is limited to diabetic neuropathy only as it implies???	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part.** ODG has conducted its own evidence-based review, and has updated the individual treatment guideline on "H-wave stimulation (devices) [ODG]." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. Specifically, ODG added the phrase "or chronic soft tissue inflammation" to expand the indications to conditions in addition to diabetic neuropathy. **Disagree** with the remaining recommended edits for the reasons set forth in the **r**esponse to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic	See action taken in connection with comment submitted by Ryan Heaney, President, Electronic Waveform Lab, Inc., dated August 14, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Transcutaneous Electrotherapy [DWC] H-wave stimulation (devices) [ODG].

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Transcutaneous Electrotherapy [DWC] Interferential Current Stimulation [ODG]***	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommendation on ***Interferential Therapy Units*** states "Not generally recommended…." Commenter inquires as to the meaning of this statement. Commenter adds that there is no definition as to what "generally" means. Commenter references page 77 of the guidelines. Commenter adds that the ACOEM Chronic Pain Update does not recommend ***Interferential Therapy Units***. The guideline contains "Two recommendations [and] 2 moderate quality RCTs."	James E. Lessenger, M.D. August 4, 2008	**Agreed.** ODG has revised the evidence-base and has updated its guideline individual treatment topic guideline on Interferential Current Stimulation. DWC **agrees** with the updated version and proposes to adopt the updated version of ODG's guideline in its adapted version of its chronic pain medical treatment guidelines, version dated, October 23, 2008.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Transcutaneous Electrotherapy [DWC]***, ***Interferential Current Stimulation [ODG]***, has been revised at page 123, as follows: **"Interferential Current Stimulation (ICS) ~~[ODG]~~** "Not ~~generally~~ recommended as an isolated intervention. There is no quality evidence of effectiveness except in conjunction with recommended treatments, including return to work, exercise and medications, and limited evidence of improvement on those recommended treatments alone. The randomized trials that have evaluated the effectiveness of this treatment have included studies for back pain, jaw pain, soft tissue shoulder pain, cervical neck pain and post-operative knee pain.

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				(Van der Heijden, 1999) (Werner, 1999) (Hurley, 2001) (Hou, 2002) (Jarit, 2003) (Hurley, 2004) (CTAF, 2005) (Burch, 2008) The findings from these trials were either negative or non-interpretable for recommendation due to poor study design and/or methodologic issues. In addition, although proposed for treatment in general for soft tissue injury or for enhancing wound or fracture healing, there is insufficient literature to support Interferential current stimulation for treatment of these conditions. There are no standardized protocols for the use of interferential therapy; and the therapy may vary according to the frequency of stimulation, the pulse duration, treatment time, and electrode-placement technique. Two recent randomized double-blind controlled trials suggested that ICS and horizontal therapy (HT) were effective in alleviating pain and disability in patients with chronic low back pain compared to placebo at 14 weeks, but not at 2 weeks. The placebo effect was

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				remarkable at the beginning of the treatment but it tended to vanish within a couple of weeks. The studies suggested that their main limitation was the heterogeneity of the low back pain subjects, with the interventions performing much better for back pain due to previous multiple vertebral osteoporotic fractures, and further studies are necessary to determine effectiveness in low back pain from other causes. (Zambito, 2006) (Zambito, 2007) A recent industry-sponsored study in the Knee Chapter concluded that interferential current therapy plus patterned muscle stimulation (using the RS-4i Stimulator) has the potential to be a more effective treatment modality than conventional low-current TENS for osteoarthritis of the knee. (Burch, 2008) This recent RCT found that either electroacupuncture or interferential electrotherapy, in combination with shoulder exercises, is equally effective in treating frozen shoulder patients. It should be noted that this study only showed the combined treatment effects with exercise as

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				compared to no treatment, so the entire positive effect could have been due to the use of exercise alone. (Cheing, 2008) See also **Sympathetic therapy**. See also **TENS, chronic pain**. "*How it works:* Paired electrodes of two independent circuits carry differing medium-frequency alternating currents so that current flowing between each pair intersects at the underlying target. The frequency allows the Interferential wave to meet low impedance when crossing the skin. Treatments involve the use of two pairs of electrodes and most units allow variation in waveform, stimulus frequency and amplitude or intensity, and the currents rise and fall at different frequencies. It is theorized that the low frequency of the interferential current causes inhibition or habituation of the nervous system, which results in muscle relaxation, suppression of pain and acceleration of healing. "*How it is different than TENS:* It has been postulated

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				that Interferential stimulation allows for deeper penetration of tissue, whereas TENS is predominantly a cutaneous or superficial stimulus. Interferential current is proposed to produce less impedance in the tissue and the intensity provided is suggested to be perceived as more comfortable. Because there is minimal skin resistance with the interferential current therapy, a maximum amount of energy goes deeper into the tissue. It also crisscrosses, as opposed to the linear application of the TENS. This crisscrossing is postulated to be more effective because it serves to confuse the nerve endings, preventing the treated area from adjusting to the current. There are no published randomized trials comparing TENS to Interferential current stimulation. "*Current US treatment coverage recommendations:* Health plans have taken a variety of positions with respect to ICS. *California Technology Assessment Forum* concluded that the treatment does not meet their

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				criteria for coverage. ~~The treatment does not meet the CTAF criteria 2-5 for the treatment of musculoskeletal pain. Interferential stimulation did meet the criterion for meeting appropriate regulatory approval.~~ (CTAF, 2005) *Aetna*~~:~~ ~~C~~consider~~ed~~s it experimental ~~and investigational for the reduction of pain and edema and all other indications~~ because its effectiveness ~~for these indications~~ has not been established. (Aetna, 2007) *United Healthcare* concluded that clinical evidence supports its use for treatment of pain or non-surgical soft tissue injuries. (United, 2007) *Humana* provides coverage for acute postoperative or post-traumatic pain, or chronic pain of at least three months duration that is not responsive to other methods of pain management. (Humana, 2008) There is considerable variance in the *BlueCross BlueShield*~~:Considered investigational/not medically necessary to provide pain relief associated with soft tissue injury,~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~musculoskeletal disorders, or in enhancing wound and fracture healing.~~ coverage recommendations, and some BC/BS licensees reference ICS as investigational/not medically necessary (BlueCross BlueShield, 2006), but others do cover it. (BC/BS_TN, 2008) *CMS*~~:~~ ~~D~~does not directly address ~~the~~ its use. ~~of Interferential stimulator – treatment.~~ In workers' comp, Washington L&I covers these devices, but only from a single TENS supplier. (Washington, 2008) [Note: Coverage determinations by health insurance plans are not considered high quality evidence in formulating ODG recommendations, but may be provided for reference when high quality studies are not available.] ~~See also – Sympathetic therapy. See also TENS, chronic pain.~~ "**While not ~~generally~~ recommended, Patient selection criteria if Interferential stimulation is to be used anyway:** "Possibly appropriate for the following conditions if it has

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				documented and proven to be effective as directed or applied by the physician or a provider licensed to provide physical t~~herapist~~ medicine: -Pain is ineffectively controlled due to diminished effectiveness of medications; or -Pain is ineffectively controlled with medications due to side effects; or "-History of substance abuse; or "-Significant pain from postoperative ~~or acute~~ conditions limits the ability to perform exercise programs/physical therapy treatment; or "-Unresponsive to conservative measures (e.g., repositioning, heat/ice, etc.) "If those criteria are met, then a one-month trial may be appropriate to permit the physician and physical ~~therapist~~ medicine provider to study the effects and benefits. There should be evidence of increased functional improvement, less reported pain and evidence of medication reduction. A "jacket" should not be certified until after the one-

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				month trial and only with documentation that the individual cannot apply the stimulation pads alone or with the help of another available person."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Transcutaneous Electrotherapy [DWC] Interferential Current Stimulation [ODG]***	Commenter quotes from the Interferential Current Stimulation (ICS) section: *"Possibly appropriate for the following conditions if it has documented and proven to be effective as applied by a licensed physical therapist:* *- Pain is ineffectively controlled due to diminished effectiveness of medications; or* *- Pain is ineffectively controlled with medications due to side effects; or* *- History of substance abuse; or* *- Significant pain from postoperative or acute conditions limits the ability to perform exercise programs/physical therapy treatment; or* *- Unresponsive to conservative measures (e.g., repositioning, heat/ice, etc.)."* Commenter states that the guideline suggests that this electrotherapy modality could be beneficial, reduce pain, reduce medication complications, promote exercise and improve function. Commenter states that unfortunately the guideline assumes that the patient can be treated or is being treated regularly in a physical therapy clinic or that the physician may not be the appropriate treater or decision maker. Commenter requests that DWC change the language of the sentence to read: *"• Possibly appropriate for the following conditions if it has documented and proven to be effective as* **directed or applied by the physician** or ~~*applied*~~ *by a licensed physical therapist:"*	Robert R. Thauer, President Alliance for Physical Therapy, Rehabilitation & Medical Technology August 8, 2008 August 11, 2008 Written and Oral Comments	**Agree.** See response in connection with comment submitted by James E. Lessenger, M.D., dated August 4, 2008 above, in connection with same section. Moreover, DWC agrees that application of interferential stimulation may be performed by the physician and by a provider licensed to provide physical medicine.	See action taken in connection with comment submitted by James E. Lessenger, M.D., dated August 4, 2008 above, in connection with same section.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter states that the physician is responsible for treatment. He indicates that the physician determines use and efficacy of modalities, and should have the option to utilize this modality without the current restriction.			
Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Interferential Current Stimulation[ODG]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not generally recommended." Commenter points to the following language in the guideline: "While not generally recommended, Patient selection criteria if Interferential stimulation is to be used anyway. Possibly appropriate for the following conditions if it has documented and proven to be effective as applied by a licensed physical therapist: - Pain is ineffectively controlled due to diminished effectiveness of medications; or - Pain is ineffectively controlled with medications due to side effects; or - History of substance abuse; or - Significant pain from postoperative or acute conditions limits the ability to perform exercise programs/physical therapy treatment; or - Unresponsive to conservative measures (e.g., repositioning, heat/ice, etc.)." Commenter states this is very problematic. Commenter states that if it is not indicated, this should be deleted.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. Moreover, in certain instances treatment guidance is important in limited situations or to provide additional information to facilitate appropriate utilization review. ODG states that this treatment is "Not generally recommended" and this provides for occasions of limited application for the treatment. ODG does not state that the treatment "is not recommended altogether," and therefore the text of the guideline is important in the medical determination.	None.
9792.24.2(a) Chronic Pain	Commenter believes that the guideline should be concise in order to be an effective utilization review	Theodore Blatt, M.D. Medical Director ,	**Disagree.** See Response to commenter Theodore Blatt, M.D.,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Microcurrent electrical stimulation (MENS devises) [ODG]***	reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Anthem Blue Cross, July 28, 2008	Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	
Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***RS-4i sequential stimulator [ODG]***	Commenter references this guideline but makes no comment. It appears that commenter agrees with DWC's guideline.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree.**	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Electroceutical Therapy (bioelectric nerve block) [ODG]***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Neuromuscular electrical***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
stimulation (NMES devices) [DWC]				
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Trigger point injections***	Commenter states that the ***Trigger point injections*** section appears to note that they may include an anesthetic or corticosteroid. Commenter opines that this guidance is not evidence-based. Commenter adds that there is quality evidence that trigger point injections with corticosteroids are not helpful, yet it has potential adverse consequences. (Garvey 89, Porta 00) (Page 79, par 6.)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree**. After reviewing the evidence-base, ODG agrees with commenter that "there is quality evidence that trigger point injections with corticosteroids are not helpful." Thus, the "Criteria for the use of Trigger point injections" has been amended to delete the phrase "with or without steroid" as ODG upon review of the evidence concurs that inclusion of steroids with a trigger point injection does not belong in the criteria for use. DWC agrees, and the revised guideline will be included in its proposed adapted version of the chronic pain medical treatment guidelines.	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Trigger point injections***, Paragraph under "Criteria for the use of Trigger point injections at page 127 has been amended as follows: **"Trigger point injections** **"Criteria for the use of Trigger point injections:** "Trigger point injections with a local anesthetic ~~with or without steroid~~ may be recommended for the treatment of chronic low back or neck pain with myofascial pain syndrome when all of the following criteria are met: (1) Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain; (2) Symptoms have persisted for more than three months; (3) Medical management therapies such

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				as ongoing stretching exercises, physical therapy, NSAIDs and muscle relaxants have failed to control pain; (4) Radiculopathy is not present (by exam, imaging, or neuro-testing); (5) Not more than 3-4 injections per session; (6) No repeat injections unless a greater than 50% pain relief is obtained for six weeks after an injection and there is documented evidence of functional improvement; (7) Frequency should not be at an interval less than two months; (8) Trigger point injections with any substance (e.g., saline or glucose) other than local anesthetic with or without steroid are not recommended. (Colorado, 2002) (BlueCross BlueShield, 2004)"
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Trigger point injections***	Commenter states that he recently reviewed a denial of treatment prepared by a Registered Nurse and a physician reviewer. Commenter indicates that the recommended treatment was trigger point injection. Commenter states that the recommended treatment was proposed by a medical doctor with board certification in physical medicine and rehabilitation. Commenter states that the physician reviewer was also certified in PM & R. Commenter states that one doctor explained why the trigger point injections were indicated and the other explained through the R.N.	Robert L. Weinmann, M.D. President, Union of American Physicians and Dentists Independent Practice Association August 12, 2008	**Disagree.** Commenter presents a utilization review issue which is not at issue in this regulatory process. The chronic pain medical treatment guidelines as proposed provide for trigger point injections, but commenter indicates that under utilization review they still are denied. Commenter does not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	why they were not. Commenter states that the prescribing doctor's intent was to use the response to trigger point injection to determine whether or not the patient should also have an epidural block. Commenter states that unfortunately for the patient, the entire treatment protocol got scuttled based upon the ACOEM consensus. The utilization review denial does not explain who actually made the decision to deny. Commenter states that the R.N. who prepared the denial document and called the PTP determined upon reviewing selected pages in the ACOEM Guidelines, pages 300, 309, that "trigger point injections are not currently a recommended treatment modality for the treatment of neck or low back pain." The utilization reviewers determined that injections were of "questionable merit" even though the same reviewers in the same paragraph also acknowledged that the ACOEM guidelines recognize that "these injections may afford short-term improvement" but may not reduce the need for surgery later. Commenter indicates that now that both short term relief and longer term relief have been simultaneously precluded the patient is that much closer to termination of temporary disability and is still without foreseeable treatment. Commenter adds that in this case, the patient will pay the price.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Trigger point injections***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language except for the following: "Recommended only for myofascial pain syndrome as indicated below, with limited lasting value. Not recommended for typical back pain or neck pain.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Criteria for the use of Trigger point injections: Trigger point injections with a local anesthetic with or without steroid may be recommended for the treatment of chronic low back or neck pain with myofascial pain syndrome when all of the following criteria are met: (1) Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain; (2) Symptoms have persisted for more than three months; (3) Medical management therapies such as ongoing stretching exercises, physical therapy, NSAIDs and muscle relaxants have failed to control pain; (4) Radiculopathy is not present (by exam, imaging, or neuro-testing); (5) Not more than 4 injections per session; (6) No repeat injections unless a greater than 50% pain relief is obtained for six weeks after an injection and there is documented evidence of functional improvement; (7) Frequency should not be at an interval less than two months; (8) Trigger point injections with any substance (e.g., saline or glucose) other than local anesthetic with or without steroid are not recommended."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Ultrasound, therapeutic***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Not recommended."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and	Commenter addresses the treatment guideline for ***Venlafaxine*** under a hearing entitled: Off label recommendations. Commenter states that several instances of off label indications are documented in the text of the DWC Chronic Pain Guidelines, including Venlafaxine. Commenter states that in its	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree** with commenter regarding off-label recommendations. The FDA allows off-label use, and this amounts to more than half of prescriptions for many drugs. One	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, ***Venlafaxine (Effexor®)***, has been

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments ***Venlafaxine (Effexor®)***	description Venlafaxine is recommended as a first line treatment option for neuropathic pain despite not having FDA approval for this indication, only a reference for hepatic and renal consideration is listed. (Page 80, par 6.)		of the top selling drugs, Neurontin, is primarily used off-label. Where off-label use is appropriate, it should be supported by quality studies, and these studies are referenced in the ODG guidelines. ODG has conducted its own evidence-base review on "Venlafaxine (Effexor®)," and determined that venlafaxine is a treatment option for neuropathic pain. Commenter further expresses concerns regarding "first line" status in the absence of FDA indication. ODG determined based on its evidence review that it is effective for neuropathic pain and "[i]t may have an advantage over tricyclic antidepressants due to lack of anticholenergic side effects" and on this basis explains the preference for this agent over other choices. Moreover, the comment that the guideline contains "only a reference for hepatic and renal consideration" is not a substantive comment, and does not address the substance of the regulations. As previously indicated, ODG has conducted its own evidence-based review, and has updated the individual treatment guideline on "Venlafaxine (Effexor®)." DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical	modified as follows: **"Venlafaxine (Effexor®)** "Recommended as an option in first-line treatment of neuropathic pain. Venlafaxine (Effexor®) is a member of the selective serotonin and norepinephrine reuptake inhibitor (SNRIs) class of antidepressants. It has FDA approval for treatment of depression and anxiety disorders. It is off-label recommended for treatment of neuropathic pain, diabetic neuropathy, fibromyalgia, and headaches. The initial dose is generally 37.5 to 75 mg/day with a usual increase to a dose of 75 mg b.i.d or 150 mg/day of the ER formula. The maximum dose of the immediate release formulation is 375 mg/day and of the ER formula is 225 mg/day. It may have an advantage over tricyclic antidepressants due to lack of anticholenergic side effects. Dosage requirements are necessary in patients with hepatic and renal impairment. (Namaka, 2004) See also **Antidepressants for**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			treatment guidelines.	~~neuropathic~~ **chronic pain** for general guidelines, as well as specific **Venlafaxine** listing for more information and references."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Venlafaxine (Effexor®)***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended as an option in first-line treatment of neuropathic pain."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Venlafaxine (Effexor®)***	Commenter references the SNRIs (***Venlafaxine (Effexor®)*** treatment guideline contained in Part 2. Pain Intervention and Treatments of the Chronic Pain Medical Treatment Guidelines. Commenter edits the treatment guideline as follows: **"Venlafaxine ~~(Effexor®)~~** Recommended as an option in first-line treatment of neuropathic pain. Venlafaxine ~~(Effexor®)~~ is a member of the selective-serotonin reuptake inhibitor class of antidepressants. It has FDA approval for treatment of depression and anxiety disorders. It is off-label recommended for treatment of neuropathic pain, diabetic neuropathy, fibromyalgia, and headaches. The initial dose is generally 37.5 to 75 mg/day with a usual increase to a dose of 75 mg b.i.d or 150 mg/day of the ER formula. The maximum dose of the immediate release formulation is 375 mg/day and of the ER formula is 225 mg/day. It may have an advantage over tricyclic antidepressants due to lack of anticholenergic side effects. Dosage requirements are necessary in patients with hepatic and renal impairment. (Namaka, 2004) See also	Robert L. Barkin, PharmD, M.B.A.	**Disagree** with commenter's suggestion to remove the brand name of the drug. DWC agrees with ODG's practice that while major listings use generic names, ODG also includes brand names for usability. Moreover, **disagree** with the remaining recommended changes as the general editing comments are inconsistent with ODG's style and do not address the substance of the regulations.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Antidepressants for neuropathic pain."			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***White willow bark [DWC]***	Commenter references this guideline which states: "White willow bark is not recommended for chronic pain." Commenter references his previous comments about non medical treatments. Commenter requests that in addition to addressing non-medical treatment, a statement in the MTUS about necessity of providing over the counter medication and treatment would be of benefit to the UR organizations.	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Agree in part. Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above. **Agree** that the chronic pain medical treatment guidelines should address the "medical foods" issue. Commenter has previously raised this issue. See response to comment submitted by same commenter on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Nonprescription medications,*** above.	See action taken in connection with comment submitted by Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Nonprescription medications,*** above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Work conditioning, work hardening***	Commenter observes that Work Hardening and Work Conditioning Programs are an example of a serious omission in the DWC Chronic Pain Treatment Guidelines. Commenter states that they are not mentioned at all in the draft, but are well established and often accredited. Commenter opines that their absence implies not recommending, contradicting other guidelines leading to potentially unnecessary confusion. Commenter believes that an effective ban on these programs would unfairly restrict a valuable treatment option to injured California workers.	ACOEM, Barry Eisenberg, Executive Director, August 7, 2008	**Agree.** ODG has reviewed the evidence-base and has added a new individual treatment topic guideline entitled "Work conditioning, work hardening" to its guidelines. DWC **agrees** with the new individual treatment topic guideline on "Work conditioning, work hardening," as contained in the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines.	9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, has been modified by adding a new individual treatment topic guideline as follows: **"Work conditioning, work hardening** "Recommended as an option, depending on the availability of quality programs. **Criteria for admission to a Work Hardening Program:** (1) Work related

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				musculoskeletal condition with functional limitations precluding ability to safely achieve current job demands, which are in the medium or higher demand level (i.e., not clerical/sedentary work). An FCE may be required showing consistent results with maximal effort, demonstrating capacities below an employer verified physical demands analysis (PDA). (2) After treatment with an adequate trial of physical or occupational therapy with improvement followed by plateau, but not likely to benefit from continued physical or occupational therapy, or general conditioning. (3) Not a candidate where surgery or other treatments would clearly be warranted to improve function. (4) Physical and medical recovery sufficient to allow for progressive reactivation and participation for a minimum of 4 hours a day for three to five days a week. (5) A defined return to work goal agreed to by the employer & employee: (a) A documented specific job to return to with job

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				demands that exceed abilities, OR (b) Documented on-the-job training (6) The worker must be able to benefit from the program (functional and psychological limitations that are likely to improve with the program). Approval of these programs should require a screening process that includes file review, interview and testing to determine likelihood of success in the program. (7) The worker must be no more than 2 years past date of injury. Workers that have not returned to work by two years post injury may not benefit. (8) Program timelines: Work Hardening Programs should be completed in 4 weeks consecutively or less. (9) Treatment is not supported for longer than 1-2 weeks without evidence of patient compliance and demonstrated significant gains as documented by subjective and objective gains and measurable improvement in functional abilities. (10) Upon completion of a rehabilitation program (e.g.,

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				work hardening, work conditioning, outpatient medical rehabilitation) neither re-enrollment in nor repetition of the same or similar rehabilitation program is medically warranted for the same condition or injury. **ODG Physical Medicine Guidelines – Work Conditioning** 10 visits over 8 weeks See also **Physical medicine** for general guidelines. And, as with all physical medicine programs, Work Conditioning participation does not preclude concurrently being at work.**"**
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Yoga***	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended as an option only for select, highly motivated patients."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Actiq®, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments **Ziconotide**	Commenter believes that the guideline should be concise in order to be an effective utilization review reference tool. Commenter recommends striking all language after the first sentence, "Recommended for use after there is evidence of a failure of a trial of intrathecal morphine and dilaudid, and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects."	Theodore Blatt, M.D. Medical Director , Anthem Blue Cross, July 28, 2008	**Disagree.** See Response to commenter Theodore Blatt, M.D., Medical Director, Anthem Blue Cross, dated July 28, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
(Prialt®)			Actiq®, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Ziconotide (Prialt®)***	Commenter states that within these guidelines, DWC's recommend that coverage for PRIALT® (ziconotide intrathecal infusion) will require patients fail a trial of intrathecal (IT) morphine and Dilaudid®, and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects. Commenter adds that the proposed Guidelines have listed an incorrect indication for PRIALT. Commenter indicates that the proposed guidelines state, *"it [ziconotide] is FDA-approved for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of other treatments, such as systemic analgesics, adjunctive therapies, or other first-line treatment. This medication is meant to be an option for patients who are intolerant and/or refractory to intrathecal morphine."* Commenter states that Elan is concerned that there is misinformation listed in the proposed guidelines about the FDA-approved indication for PRIALT. Specifically, commenter states that the FDA has approved PRIALT for the management of severe chronic pain in patients for whom intrathecal (IT) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine. Commenter states that the approved label does not require a patient to fail "other" first-line treatment, which is not defined. Commenter adds that the label does not require that a patient fail IT morphine in order to initiate PRIALT therapy. Commenter indicates that IT morphine is one example of intolerance or refractoriness that could lead to PRIALT initiation. Commenter states that another important issue is the requirement of IT Dilaudid before allowing PRIALT. Commenter states that	Nick Poulios, Ph.D., Vice President, Pricing & Reimbursement Strategy Elan Pharmaceuticals	**Agree in part**. Commenter states that the proposed individual treatment guideline on "Ziconotide (Prialt®)" lists an incorrect indication for PRIALT. Commenter states that the proposed guidelines state, *"it [ziconotide] is FDA-approved for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of other treatments, such as systemic analgesics, adjunctive therapies, or other first-line treatment. This medication is meant to be an option for patients who are intolerant and/or refractory to intrathecal morphine."* ODG has revised its individual treatment guideline on "Ziconotide (Prialt®)." The language in the guideline is now modified by ODG to remove "*or other first-line treatment."* This modification states more correctly how PRIALT is utilized based on FDA-approved indications for PRIALT. DWC **agrees** with the updated version dated October 23, 2008 and proposes to adapt the updated version in the chronic pain medical treatment guidelines. Commenter adds that the label does not require that a patient fail	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, ***Ziconotide (Prialt®)***, has been amended as follows: **"Ziconotide (Prialt®)** "Recommended for use after there is evidence of a failure of a trial of intrathecal morphine ~~and dilaudid~~ or hydromorphone (Dilaudid), and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects. The 2007 Polyanalgesic Consensus Conference Recommendations for the Management of Pain by Intrathecal Drug Delivery concluded that ziconotide should be updated to a first-line intrathecal drug. "Ziconotide (Prialt®) is a synthetic calcium channel blocker that is delivered intrathecally, offering a non-opioid option for treatment of chronic pain, and possibly, spasticity

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	Dilaudid is not FDA approved for delivery via an IT implanted pump. Commenter states that to require a trial failure of this agent would support off-label use of this agent without substantial randomized clinical trial support. Commenter states that currently, the only FDA approved medications for IT therapy to manage chronic pain are morphine and PRIALT. Commenter states that athough Elan believes that the approved FDA label enables firstline usage of IT Prialt, they are concerned that the proposed Guidelines are recommending off-label use of another agent prior to usage of a therapy approved for such indication. Commenter states that in fact, no scientific evidence exists that indicate patients will benefit from this drug only after failure of morphine and dilaudid agents. Commenter indicates that one additional point of concern is that DWC's proposed policy makes no mention of those patients whose pain has become refractory to treatment with morphine. Commenter reiterates that as indicated in their package insert, PRIALT® (ziconotide) is not only approved to treat patients who are intolerant of systemic analgesics, adjunctive therapies, or IT morphine, the drug is also approved to treat patients who become refractory to these treatments. Commenter has enclosed a copy of the prescribing information for PRIALT. Commenter summarizes by stating that PRIALT should be covered by the DWC guidelines in accordance with the drug's FDA approved package insert. Commenter indicates that the inclusion of this therapy in DWC's coverage guidelines will ensure that injured California workers have access to this important therapeutic option for IT chronic pain management.		IT morphine in order to initiate PRIALT therapy. Commenter indicates that IT morphine is one example of intolerance or refractoriness that could lead to PRIALT initiation. DWC **disagrees.** Based on ODG's evidence-based review, use of PRIALT is meant to be an option for patients who are intolerant and/or REFRACTORY to intrathecal morphine. Commenter states that Dilaudid is not FDA approved for delivery via an IT implanted pump. Commenter states that to require a trial failure of this agent would support off-label use of this agent without substantial randomized clinical trial support. Commenter states that currently, the only FDA approved medications for IT therapy to manage chronic pain are morphine and PRIALT. DWC **disagrees**. ODG has performed an evidence-based review and finds evidence for intrathecal Dilaudid, even though this usage is off-label and not FDA approved for this purpose. Commenter states that although Elan believes that the approved FDA label enables first line usage of IT Prialt, they are concerned that the proposed individual treatment guideline on "Ziconotide	associated with spinal cord trauma. It is FDA-approved for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of other treatments, such as systemic analgesics, adjunctive therapies~~, or other first-line treatment~~. This medication is meant to be an option for patients who are intolerant and/or refractory to intrathecal morphine. The advantage of the medication is that it is considered non-addictive. Current case reports have described many challenges in converting from morphine to ziconotide, including inadequate analgesia, adverse medication effects, and opioid withdrawal symptoms. An option for treatment is combining ziconotide with other currently available intrathecal medications, although this has not been studied in placebo-controlled trials. "*Adverse effects:* Prialt has been associated with severe CNS-related adverse effects, and a "black-box" warning

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			(Prialt®)" is recommending off-label use of another agent prior to usage of a therapy approved for such indication. DWC **disagrees.** FDA labeling does not enable first line use of PRIALT. Furthermore, if there is evidence to show the utility of a treatment, independent of FDA labeling then, the scientific evidence can be used to formulate treatment guidelines.	has been issued in this regard. Neurological warnings include hallucinations, paranoid ideation, hostility, delirium, psychosis, manic reactions and decreased alertness. Certain patients may be at increased risk for psychiatric side effects including those with pre-existing history of depression with risk of suicide and patients with pre-existing psychosis. Cognitive impairment was noted in approximately 30% of patients in clinical trials, and this symptom was found to be reversible within about two weeks of discontinuation. Prialt is contraindicated in patients with a pre-existing history of psychosis. Prialt can be discontinued abruptly without evidence of withdrawal effects in the presence of serious adverse events. "*Dosage requirements:* The current recommendations suggested by the manufacturer for this medication include a low initial infusion rate (0.1 mcg/hour for a total of 2.4 mcg/day) and limiting

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				infusion increases to 2-3 times a week. Current drug trials have evaluated the efficacy of the medication for a 3-week duration only, but preliminary trials suggested that analgesic efficacy would be maintained long-term in open label trials. "*Post-marketing dose recommendations:* Post-marketing, an expert consensus-panel recommended a starting dose of 0.5 mcg/24 hours with upward titration of no more than 0.5 mcg/week due to increased risk of adverse effects with higher doses. (Fisher, 2005) "*Filling intervals:* The reservoir should be refilled initially at 14 days and at 40-day intervals thereafter if the drug is diluted (60 days if undiluted). "*Other precautions:* This medication is associated with elevation of serum creatinine kinase, with risk factors including male gender and concomitant use of anti-depressants, anti-convulsants and intrathecal morphine.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				This lab value should be monitored at least bi-weekly for the first month and at monthly intervals thereafter. Symptoms of myalgia include myasthenia, muscle cramps and unusual fatigue. (Thompson, 2006) (Wermeling 2005) (Lyseng-Williamson, 2006) (Lynch, 2006) ~~(Deer, 2007)~~ (Rauck, 2006) (Deer, 2007) See Intrathecal drug delivery systems, medications."
9792.24.2(e)	Commenter states that upon careful review of Section 9292.24.2, it appears as though a further caveat, clarifying when the chronic pain regulation chapter applies would be helpful to stakeholders. Commenter states that while the agency has provided direction regarding what applies in several scenarios, it is not clear that the chronic pain chapter applies in the event that the treatment being requested is only addressed in that chapter. Commenter suggests the following language: "e) When the treatment being requested is addressed in the chronic pain medical treatment regulations but is not addressed elsewhere, the chronic pain medical treatment guideline shall apply."	N. William Fehrenbach, Director, State Government Affairs Medtronic August 10, 2008	**Disagree** with commenter request that the chronic pain medical treatment guidelines provide that if the chronic pain has a treatment that is not addressed in the clinical topics guidelines the chronic pain medical treatment guidelines apply. The modification as suggested by the commenter would make the chronic pain guidelines applicable when the patient has not yet been diagnosed with chronic pain. It is noted that The MTUS currently states that the chronic pain medical treatment guidelines apply when chronic pain is diagnosed by application of the clinical topics guidelines. The clinical topics make it clear when chronic pain is diagnosed, i.e., when the patient fails to recover as determined by following the clinical topics algorithms. Thus, until chronic pain is diagnosed,	None.

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			only the clinical topics guidelines apply. If the condition is not addressed in the clinical topics guidelines, then other guidelines apply pursuant to section 9792.21(c). Using the chronic pain chapter before the patient has yet failed to recover is not appropriate. Once it is determined that the chronic pain medical treatment guidelines are applicable, the clinical topics guidelines can be applied for the specific body part where the chronic pain medical treatment guidelines do not address, including acute conditions and/or exacerbations.	
9792.24.3 (General Comment)	Commenter is concerned about the DWC adopting an older version of the ODG guidelines. Commenter points out that there have been changes to the ODG guidelines during the spring and that these changes are significant. Commenter requests that if for some reason DWC cannot adopt the most current version of the ODG guidelines, there be another 15 day revision to incorporate the changes.	Kristine Shultz, California Chiropractic Association, August 12, 2008, Written Comment	**Agree.** See response to comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.	See action taken in connection with comment submitted by Frank D. Navarro, Associate Director, CES, California Medical Association, dated August 11, 2008, above.
9792.24.3	Commenter states that Labor Code Section 4604.5(b) requires the Medical Treatment Utilization Schedule to be scientifically and evidence-based, nationally recognized and peer reviewed. Commenter further states that the purpose and function of the MEEAC is to provide recommendations to the Medical Director to revise, update, or supplement the medical treatment utilization schedule (§§ 9792.23(a) and (c)). Commenter adds that the task of the MEEAC is to review the evidence base of proposed treatment guidelines to determine whether the guidelines are scientifically and evidence-based, and nationally recognized by the medical community. (§	California Workers' Compensation Institute Brenda Ramirez, Claims and Medical Director August 12, 2008	**Disagree.** DWC believes that the postsurgical medical treatment guidelines does meet the requirements of the statute that the guidelines be "scientifically and evidence-based, peer reviewed and meeting a nationally recognized standard." In the ISOR, DWC stated, in relevant part, at pp. 44-46 as follows: "Labor Code section 4604.5(d)(1) provides that for injuries occurring	None.

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	9792.23(c)(1)). Commenter states that to evaluate the evidence underlying the proposed treatment guidelines, the MEEAC must apply the ACOEM strength of evidence rating methodology to the underlying scientific evidence (§ 9792.22(c)). Commenter adds that the methodology requires the grading of any supporting medical evidence in accordance with the scale contained in § 9792.22. Commenter indicates that the proposal for the modification or augmentation of the MTUS must follow the dictates of the regulations and must provide the regulated community with a scientific rationale sufficient to support the application of the presumption of correctness to any new treatment guidelines. Commenter notes that as indicated in comments on proposed chronic pain guidelines, injured workers, employers, claims administrators, medical providers, the WCALJs, the appeals board and the appellate courts depend on this scientific assessment in order to apply the presumption and understand the weight of the evidence being presented with regard to specific modalities of medical care. Commenter states that the proposed postsurgical treatment guidelines are described as being based on ODG's physical medicine guidelines, however , commenter states that the ODG physical medicine guidelines include little on what physical medicine is medically necessary to facilitate postsurgical improvement and there are few if any studies in the ODG Guidelines references in Appendix E that address this subject. Commenter states that it appears that ODG headings have been revised and adopted from the ODG's guidelines on physical medicine (Note: not on **post-**		on and after January 1, 2004, an injured worker shall be entitled to no more than 24 chiropractic, 24 occupational therapy, and 24 physical therapy visits per industrial injury. Labor Code section 4604.5(d)(3), as amended by Assembly Bill 1073 (Statute 2007, Chapter 621), creates an exception to the 24 visit cap by providing that the 24 visit limitation does "not apply to visits for postsurgical physical medicine and postsurgical physical medicine services provided in compliance with a postsurgical treatment utilization schedule established by the administrative director pursuant to section 5307.27." Pursuant to AB 1073 and in order to implement, interpret, and make specific and carry out the provisions of Labor Code section 4604.5(d)(3), the Administrative Director proposes to adopt the proposed guidelines for postsurgical physical medicine which supersedes the limit of 24 visits for physical therapy, occupational therapy, and chiropractic treatment found in Labor Code section 4604.5(d)(1). "The proposed Postsurgical Treatment Guidelines, section 9792.24.3, et al., are adapted from the Work Loss Data Institute's Official Disability Guidelines	

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	surgical physical therapy guidelines) but the introductions to the body parts and the numbers of visits, and the time periods are not based on evidence regarding postsurgical physical medicine treatment. Commenter also states that in the proposed postsurgical treatment guideline, the DWC has supplemented the ODG-based guidelines on surgeries with "additional surgeries" and provided in the Initial Statement of Reasons Appendix C, evidence based reviews performed per the MTUS standards. Commenter observes that these evidence-based reviews also found insufficient evidence on which to base any recommendations for postsurgical physical medicine treatment. Commenter states that while the current MTUS contains individual treatment guidelines that are graded as 'Insufficient' (I) because there is inadequate scientific evidence supporting a recommendation, the notion of adding an entire guideline for a complete condition or course of care that is based on insufficient medical evidence turns the statute in its head. Commenter adds that the proposed post-surgical physical medicine guideline that for each surgery listed notes insufficient evidence supporting the recommendations elevates these insufficient recommendations to the level of minimum legal requirements merely by being included in Labor Code section 5307.27. Commenter opines that by including these unsupported guidelines, the Administrative Director will give them false weight by operation of the presumption contained in section 4604.5. Commenter opines that the proposed guideline fails the statutory test of section 5307.5 and cannot be included as part of the medical treatment utilization schedule. Commenter states that the dearth of relevant studies		(ODG) Treatment in Workers' Comp, with the permission of the Work Loss Data Institute. (See, letter from Work Loss Data Institute, dated March 13, 2008.) The Work Loss Data Institute has authorized DWC to use a hardcopy excerpt from the chapter procedure summaries (Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers' Comp-Excerpt from the Chapter Procedures Summaries (ODG Physical Medicine Guidelines), version dated November 12, 2007 [Now as updated October 23, 2008]) to identify all surgeries and adapt their individual postsurgical physical medicine treatment guidelines into the DWC's postsurgical treatment guidelines (DWC 2008) in compliance with the requirements of Labor Code section 4604.5(d)(3). ... The selection of the ODG Physical Medicine Guidelines was based not only on the fact that the ODG guidelines were determined to meet the requirements of the statute (Lab. Code, § 5307.27) by RAND in its publication entitled, *Evaluating Medical Treatment Guideline Sets for Injured Workers in California,* RAND Institute for Civil Justice and RAND Health, 2005 (2005 RAND Report; see, Table 4, p. 21; Table 4.2, p. 27), but primarily upon a thorough	

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	leaves only fundamental questions regarding the lack of evidence underlying the proposed guidelines. Commenter also states that the elements contained in section 9792.22(c)(1)(a) "Table A" are indispensable to the determination of the strength of evidence for the ODG guidelines, and this rationale leads to the grading scale contained in "Table B." Commenter argues that without scientific evidence, the end product is a set of unsupported, inadequate treatment recommendations that have not met the basic statutory criteria for inclusion in the MTUS and are consequently unlawful. Commenter argues that the Administrative Director may not adopt an unlawful schedule.		review of their entire Physical Medicine Guidelines by the Division of Workers Compensation (DWC), the Medical Evidence Evaluation Advisory Committee (MEEAC), and designated subject matter experts. "In applying the requirements of this section, the MEEAC and designated subject matter experts conducted a thorough review of ODG's Physical Medicine Guidelines. The MEEAC noted that ODG's Physical Medicine Guidelines needed supplementation to include additional surgeries. Evidence-based reviews (EBRs) were conducted on these surgical areas to determine the most appropriate treatments. The EBRs reflected insufficient evidence for or against postsurgical physical medicine in many cases. Nevertheless, evidence-based medicine includes making recommendations even when there is insufficient evidence. " 'Guidelines built on synthesis of the evidence, but go one step further to provide formal conclusions or recommendations about appropriate and necessary care for specific types of patients.'" *Crossing the Quality*	

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			Chasm: A New Health System for the 21st Century/Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, D.C., Fifth Printing, June 2004, p. 151. "Therefore, the first step of developing a clinical practice guideline is to do the evidence-based reviews. The second step involves "…reli[ance] on expert panels to arrive at specific clinical conclusions. Judgment must be exercised in this process because the evidence base is sometimes weak or conflicting, or lacking in the specificity needed to develop recommendations useful for making decisions about individual patients in particular settings (Lohr, et al., 1998)." *Crossing the Quality Chasm*, Institute of Medicine, (2001), p. 151. "Thus, the MEEAC made recommendations to develop the guidelines, and the recommendations are included in DWC's postsurgical treatment guidelines. The postsurgical physical medicine treatment guidelines adapted directly from ODG are labeled '**[ODG].**' The postsurgical physical medicine treatment guidelines not adapted directly from ODG but recommended by the DWC are	

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			labeled '**[DWC].**' (See, Appendix C—Postsurgical Treatment Guidelines (DWC 2008), Evidence-Based Reviews) "Further, in making recommendations to the Administrative Director via the Medical Director to supplement the MTUS, the MEEAC is responsible for evaluating the developed guidelines to insure that the guidelines conform to the framework of the MTUS. The MEEAC must further take into consideration Labor Code 4604.5(a), which provides that the MTUS is presumed to be 'correct on the issue of extent and scope of medical treatment,' provided to injured employees. Clarity in guidelines facilitates appropriate treatment which is presumed to be correct pursuant to the Labor Code and avoids delayed treatment, thus encouraging prompt recovery and reduced disability. "Moreover, because the postsurgical treatment guidelines constitute an exception to the 24 physical therapy visits per industrial injury pursuant to Labor Code section 4604.5(d)(1), it was necessary for DWC, in order to implement, interpret and make specific and carry out the provisions of Labor Code section	

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			4604.5(d)(3), to define a postsurgical physical medicine period. In order to comply with the requirement of the statute, the MEEAC and designated subject matter experts defined the postsurgical physical medicine period for the specified surgeries. The postsurgical physical medicine period frames the time interval that is needed for an injured worker to recover from the effects of the specific surgery that he or she experienced. This time is exempt from the 24-visit cap. Upon reaching the end of the time interval, the postsurgical treatment guidelines cease to apply thereby reverting back to the 24-visit cap." Thus, DWC **disagrees** with commenter's statement that the postsurgical guidelines do not meet the requirements of the statute.	
9792.24.3	Commenter states that CMA thanks the DWC for addressing this issue and supports the proposed Post Surgical Treatment Guidelines as written.	Frank D. Navarro, Associate Director, CES, California Medical Association, Written & Oral Comments, August 11, 2008 and August 12, 2008	**Agree.**	None.
9792.24.3	Commenter states that the members of the California Orthopaedic Association appreciate all of the efforts of the Division to adopt treatment guidelines which represent the very best treatment for injured workers.	Mark Wellisch, M.D., President, California Orthopaedic	**Agree.**	None.

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	Commenter understands what a major undertaking it is to evaluate and assess treatment guidelines. Commenter indicates that as the sponsor of AB 1073, COA supports the Division's efforts to adopt postsurgical treatment guidelines. Commenter states that the guidelines will clarify the importance of postsurgical rehabilitation services for optimal recovery and to reduce disability. Commenter particularly support the way in which these guidelines were developed - adapting a published set of guidelines along with recommendations from the Medical Evidence Evaluation Advisory Committee (MEEAC).	Association, August 11, 2008 Diane Przepiorski, Executive Director, California Orthopaedic Association Oral Comment, August 12, 2008		
9792.24.3(a)	Commenter states that AB 1073, in Labor Code section 4604.5 (d)(1), set a cap of 24 physical medicine visits for injuries sustained after 2003, notwithstanding the MTUS. Commenter adds that per paragraph (2), that cap does not apply to postsurgical physical medicine and rehabilitation services provided in compliance with a postsurgical treatment utilization schedule established by the administrative director in accordance with Labor Code section 5307.27. Commenter observes that the Administrative Director appears to have two possible options to address this conundrum. One option is to wait to adopt postsurgical guidelines until there are scientific medical studies on which to base guidelines that can address, at a minimum, the frequency, duration, intensity, and appropriateness of all commonly performed postsurgical physical medicine and rehabilitation procedures and modalities. Commenter indicates that the other option is to modify the proposed language in the postsurgical treatment guidelines to allow postsurgical physical medicine and rehabilitation services in accordance with the MTUS clinical topic sections 9792.23.1 through 9792.24 without regard to the 24 visit caps.	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Disagree.** Commenter argues what she perceives to be a statutory "conundrum." In her view the "conundrum" is the choice between the statutory *cap* (Lab. Code, § 4604.5(d)(1) versus the *exception to the cap* (Lab. Code, § 4604.5(d)(3)). Commenter is critical of the statute, although it appears that she argues that the proposed regulations have caused the "conundrum." **Disagree**. DWC finds no "conundrum." The statute is clear that chiropractic, occupational therapy, and physical therapy visits are limited to 24 visits per industrial injury pursuant to Labor Code section 4604.5(d)(1). However, if surgery is performed, the injured worker is entitled to further physical therapy, occupational therapy, and chiropractic treatment in compliance with a postsurgical treatment utilization schedule	None.

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	Commenter states that while AB 1073 provides that the 24 visit physical medicine caps will not apply for services provided in compliance with a postsurgical treatment utilization schedule established by the administrative director, it does not prohibit the application of the clinical topic sections in the Medical Treatment Utilization Schedule to postsurgical physical medicine services. A postsurgical treatment utilization schedule can identify the surgeries exempt from the caps, but need not overrule the clinical topic sections that address postsurgical physical medicine services. Requests for other postsurgical physical medicine services can be considered pursuant to section 9792.25. [Commenter states that to accomplish the second option, the Administrative Director can adopt the changes recommended below and delete the remainder of the section—Recommendations charted in under specific sections.] Commenter recommends that the Administrative Director wait to adopt postsurgical guidelines until there are scientific medical studies on which to base guidelines that can address, at a minimum, the frequency, duration, intensity, and appropriateness of all commonly performed postsurgical physical medicine and rehabilitation procedures and modalities. Alternatively, commenter recommends that the Administrative Director modify the proposed language to allow postsurgical physical medicine and rehabilitation services in accordance with clinical topic sections 9792.23.1 through 9792.24 without regard to the 24 visit limitations imposed on injuries sustained after 2003 by Labor Code section 4604.5(d)(1).		established by the administrative director pursuant to Labor Code section 4604.5(d)(3). The proposed guidelines for postsurgical physical medicine which supersede the limit of 24 visits for physical therapy, occupational therapy, and chiropractic treatment are proposed pursuant the statute (Lab, Code § 4604.5(d)(3)), and the proposed regulations are intended to implement, interpret, and make specific and carry out the provisions of Labor Code section 4604.5(d)(3). See also, response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008 on Section 9792.24.3, above and ISOR at pp. 44-46. Commenter presents two options as the solution to her perceived "conundrum." Commenter first suggests that the Administrative Director wait to adopt postsurgical guidelines until there are scientific medical studies on which to base guidelines that can address, at a minimum, the frequency, duration, intensity, and appropriateness of all commonly performed postsurgical physical medicine and rehabilitation procedures and modalities. **Disagree** with commenter's first option. Commenter's first option is flawed	

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			because the statute requires that the Admninstrative Director adopt postsurgical treatment guidelines. Evidence-based medicine is the evaluation of the current available evidence, including a determination that the evidence is insufficient. As the postsurgical treatment guidelines cover a very broad range of surgeries, the scientific evidence will accumulate incrementally and gradually. The purpose of treatment guidelines is to survey the state of current evidence and how it applies to treatment decisions and policies at the present time. Evidence-based medicine takes into consideration that research is ongoing, and as evidence accumulates, then treatment guidelines will need to be updated, as required by the MTUS. Furthermore, lack of evidence does not prevent creation of evidence-based treatment guidelines. It is through the evidence-based review process (e.g., when the search is conducted) that a determination can be made as to whether or not evidence exists. In fact, evidence-based medicine includes making recommendations even when there is insufficient evidence. "Guidelines built on synthesis of the evidence, but go one step further to provide formal conclusions or recommendations	

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			about appropriate and necessary care for specific types of patients." *Crossing the Quality Chasm: A New Health System for the 21st Century/Committee on Quality of Health Care in America,* Institute of Medicine, National Academy Press, Washington, D.C., Fifth Printing, June 2004, p. 151. Therefore, the first step of developing a clinical practice guideline is to do the evidence-based reviews. The second step involves "…reli[ance] on expert panels to arrive at specific clinical conclusions. Judgment must be exercised in this process because the evidence base is sometimes weak or conflicting, or lacking in the specificity needed to develop recommendations useful for making decisions about individual patients in particular settings (Lohr et al., 1998)." *Crossing the Quality Chasm*, Institute of Medicine, (2001), p. 151. (See ISOR at p. 45.) Commenter's second suggestion, in the alternative, is "to modify the proposed language in the postsurgical treatment guidelines to allow postsurgical physical medicine and rehabilitation services in accordance with the MTUS clinical topic sections 9792.23.1 through 9792.24 without	

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			regard to the 24 visit caps." DWC also **disagrees** with commenter's second option to use the clinical topics sections (meaning ACOEM) to define postsurgical. Using the clinical topics sections in lieu of a specifically crafted guideline will create disputes over treatment decisions, which will in turn result in delay of treatment at the very specific time when postsurgical care is most needed. A delay, due to unclear or disputed application of clinical topics, will defeat the intention of the statute to provide for postsurgical rehabilitation when is most needed. Moreover, there is little guidance on postsurgical treatment in the clinical topics, as the ACOEM chapters defer to the judgment of the surgeon and simply mentions "postoperative care" (see algorithm 4 in each chapter).	
9792.24.3(a)(1)	Commenter recommends that § 9792.24.3(a)(1) setting forth the definition of the term "general course of therapy," be deleted as unnecessary under the changes recommended by the CWCI above.	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Disagree.** Commenter's proposed changes are not accepted for the reasons set forth in connection with the response to the same commenter on section 9792.24.3(a) above.	None.
9792.24.3(a)(2)	Commenter recommends that § 9792.24.3 (a)(2) setting forth the definition of the term "initial course of therapy," be deleted as unnecessary under the changes recommended by CWCI.	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Disagree.** Commenter's proposed changes are not accepted for the reasons set forth in connection with the response to the same commenter on section 9792.24.3(a) above.	None.

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9792.24.3(a)(3)	Commenter recommends that § 9792.24.3 (a)(3) setting forth the definition of the term "postsurgical physical medicine period" be deleted as unnecessary under the changes recommended by CWCI.	Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008	**Disagree.** Commenter's proposed changes are not accepted for the reasons set forth in connection with the response to the same commenter on section 9792.24.3(a) above.	None.
9792.24.3(a)(3)	Commenter states that the postsurgical physical medicine guidelines contain a number of deviations from the ODG, as well as the addition of a "postsurgical physical medicine treatment period." Commenter states that the addition of these "postsurgical physical medicine treatment period" is confusing in the context of the overall structure of the ODG material. Commenter suggests that the DWCs deviations be removed.	Harry J. Monroe, Director of Government Relations Coventry Health Care August 12, 2008	**Disagree.** DWC **disagrees** with the commenter's recommendation to remove "postsurgical physical medicine treatment period," which commenter opines deviates from ODG's guidelines. As indicated in the Initial Statement of Reasons (ISOR), the postsurgical physical medicine period was defined because it was not provided for in the Current Procedural Terminology 2008 (CPT 2008). The CPT 2008 sets forth surgery guidelines, and refers to a "CPT Surgical Package Definition." (CPT 2008, p. 47) The CPT surgical package definition encompasses all care directly provided as part of any surgery. It involves "[t]ypical postoperative follow-up care" (CPT 2008, p. 47) however, it does not discuss postoperative physical medicine or the period of time needed to achieve postsurgical physical medicine goals. "The services provided by a physician to any patient by their very nature are variable." (CPT 2008, p. 47) The postsurgical package concept contains items that occur with	None.

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			every surgery. The ISOR indicated that it is important to note that physical medicine is not needed following every surgery. For this reason, physical medicine is not included in the postsurgical package concept. The guidelines define the "postsurgical physical medicine period" as the time frame that is needed for postsurgical treatment, beginning with the date of the procedure and ending at the time specified for the specific surgery, in the postsurgical physical medicine treatment recommendations set forth in subdivision (d) of this section. For this reason, proposed section 9792.24.3(d) sets forth the postsurgical physical medicine recommendations, which indicates the expected frequency and duration of therapy specific to the type of surgery performed. During the healing process, there is also variability such that some patients require no physical medicine and other patients require intensive efforts to restore function with physical medicine. The ISOR further indicated that following each surgery there is a time interval where physical medicine can be provided to restore optimal form and function. The time intervals will depend on the nature of the surgery and the patient. The deviation is necessary because the	

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			ODG guidelines do not provide for this concept which is necessary to apply the statute.	
9792.24.3(a)(3)	Commenter indicates that the purpose of the "postsurgical physical medicine period", in subdiv. (a)(3) is not apparent. Commenter states that if such a period has a purpose, clarification must be provided as to how these time periods were determined. Commenter indicates that the Global Period provided in the CPT and the OWC's OMFS for each surgical procedure might bear looking at and be utilized if it is evidence based. Commenter adds that the fact that all but a very few of the post-surgical periods are six months makes them appear to be arbitrarily set. Commenter opines that this apparent arbitrary time setting is further demonstrated by the statement that any unnamed procedure in the guideline will have a six month "postsurgical physical medicine period." Commenter states that all of the periods appear to extend for months beyond the additional physical medicine course of therapy. Commenter is concerned that extending the "postsurgical physical medicine period" beyond the "General Course of Therapy periods" will result in the number of visits listed in the Frequency/ Duration column becoming the floor rather than the expectation for recovery and additional visits will then be requested to continue throughout the "postsurgical physical medicine period." Commenter recognizes that functional improvement must be shown to request continued visits, but states that improvement can be in the eye of the beholder or the reporter. Commenter states that there is no level of required improvement that must be met for continued therapy, so insignificant or truly non-existent progress could be used to justify continued therapy.	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** With regard to the "postsurgical physical medicine period," **disagree** for the reasons set forth in the response to Harry J. Monroe, Director of Government Relations, Coventry Health Care, dated August 12, 2008, above. Moreover, in the absence of peer-reviewed, scientific evidence, and in order to apply the statutory requirements to provide for postsurgical guidelines, the postsurgical physical medicine period was determined through consensus, which is required after review of the available evidence. Physical medicine following surgery is not always necessary, and each course of post-operative therapy is variable with some surgeries needing more than others. Even with injuries falling under the 24-cap, many patients do not need any therapy. The utilization review process will utilize the postsurgical treatment guidelines to facilitate optimal postsurgical rehabilitation. Also, functional improvement is defined in the proposed regulations (§ 9792.20(f)), and "insignificant" progress is not functional improvement per the commenter's description of functional improvement.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.3(a)(3)	Commenter urges that a statement be added to the guidelines to address those surgeries not included in the guidelines or circumstances when a particular injured worker requires more postsurgical rehabilitation services than specified in the guidelines. Commenter states that without this statement, he believes that, just as in the past, carriers will literally implement the guidelines. Commenter opines that this may make it difficult or impossible for treating physicians or even Workers' Compensation judges to approve additional physical medicine rehabilitation services even if they believe additional services are warranted. Commenter opines that for clarity, he believes language needs to be added to regulations to address those circumstances. Commenter recommends the addition of the following language: *"The required postsurgical rehabilitation services for optimal recovery can vary from one patient to another based on the complexity of their injury, co-morbidities, or other conditions of the injured worker. These guidelines are intended to provide guidance in the postsurgical rehabilitation services that may be required, but they are just guidelines. The guidelines are not intended to imply that surgeries not included in the guidelines will never require postsurgical rehabilitation or that some injured workers may need more postsurgical rehabilitation services than listed in the guidelines. These situations should be decided on a case-by-case basis with consultation with the treating physician."*	Mark Wellisch, M.D., President California Orthopaedic Association August 11, 2008 Diane Przepiorski Executive Director Oral Comment August 12, 2008	**Agree in part.** DWC **agrees** with the comment that the postsurgical treatment guidelines should contain language "to address those surgeries not included in the guidelines or circumstances when a particular injured worker requires more postsurgical rehabilitation services than specified in the guidelines." DWC **disagrees** that the postsurgical treatment guidelines do not contain language addressing these issues. Section 9792.24.3(a)(3) addresses "surgeries not included in the guidelines," by specifically stating in the last sentence of the section: "For all surgeries not covered by these guidelines the postsurgical physical medicine period is six (6) months." Moreover, Section 9792.24.3(c)(2) addresses commenter's concerns regarding "circumstances when a particular injured worker requires more postsurgical rehabilitation services than specified in the guidelines," by stating: "The medical necessity for postsurgical physical medicine treatment for any given patient is dependent on, but not limited to, such factors as the comorbid medical conditions; prior pathology and/or surgery involving same body part; nature, number and complexities of surgical procedure(s) undertaken; presence of surgical complications; and the	None.

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			patient's essential work functions." Thus, it is clear that the postsurgical guidelines contain language that addresses the medical necessity of postoperative physical medicine, and commenter's suggested language is not necessary.	
9792.24.3(a)(5)	Commenter states that there is no evidence presented and there are no recommendations for the content of the visits. Commenter states that a "visit" is not an assessable treatment, as the content of visits is highly variable. Commenter indicates that research on physical therapy typically tests specific modalities or exercises rather than "visits." Commenter notes that in the latter case, standard protocols would have to be used to demonstrate a reproducible effect or a dose-response effect. Commenter states that this is a critical problem as physical medicine constituted a major part of expenditures prior to reforms and still exceeds evidence-based recommendations in many cases.	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree**. The term "visits" originates from the enabling statute, Labor Code section 4604.5(d)(3), which gives rise to the postsurgical treatment guidelines regulations.	None.
9792.24.3(b)(1)	Commenter states this section provides the Postsurgical Physical Medicine Period (as defined in section 9792.24.3 (a) (3)) treatment reverts back to the applicable 24 visit limit. Commenter states that if the 24 visit limit has been removed for post surgical patients, she is confused about what 24 visit limit is being referred to. Commenter also questions whether if there is a limit after the six months, does this mean that the injured worker is entitled to an additional 24 visits beyond what they already received?	Nancy Rothenberg, Vice President PTPN August 11, 2008	**Disagree.** Pursuant to Labor Code section 4604.5(d)(1) the 24-visit cap applies to all chiropractic, occupational therapy, and physical therapy visits per industrial injury provided in connection with surgeries as defined in the postsurgical treatment guidelines. The postsurgical treatment guidelines create an exception to the 24-visit cap as defined by the postsurgical physical medicine period provided in section 9792.24.3(d). Section 9792.24.3(b)(1) defines the application of the postsurgical treatment guidelines pursuant to	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			the requirements of the statute (Lab. Code, § 4604.5(d)(3)), and clarifies that at the end of the postsurgical physical medicine period, treatment reverts back to the applicable 24-visit limitation for chiropractic, occupational and physical therapy pursuant to Labor Code section 4604.5(d)(1). It is noted that the 24-visit cap applies for the duration of the workers' compensation claim. The postsurgical treatment guidelines provide an exception to that cap as provided by Labor Code section 4604.5(d)(1).	
9792.24.3(b)(1)	Commenter states that this section states that following the Postsurgical Physical Medicine Period (as defined in section 9792.24.3 (a) (3)) treatment reverts back to the applicable 24 visit limit. Commenter states that with the signing of AB 1073, the 24 visit limit was removed for post-surgical patients and it is unclear that an injured worker may revert back to a treatment limit that never applied to the injury. Commenter states that in addition, the proposed language states that there is a limit after the six month postsurgical physical medicine period. Commenter seeks clarification on whether the injured worker is entitled to an additional 24 visits beyond what they have already received.	Tameka Island, Executive Associate California Physical Therapy Association August 12, 2008 Written Comment	**Disagree.** See response to Nancy Rothenberg, Vice President, PTPN, dated August 11, 2008 on the issue of proposed section 9792.24.3(b)(1), above.	None.
9792.24.3(b)(1)	Commenter states that this section states that the following postsurgical physical medicine treatment period as defined in Section 9792.24.3(a)(3) reverts back to the applicable 24-visit limit. Commenter questions if the 24-visit limit has been removed statutorily for postsurgical patients, how can one revert back to the treatment limit that never applied to that injury? Commenter also questions if there is a	Richard Katz California Physical Therapy Association August 11, 2008 Oral Comment	**Disagree.** See response to Nancy Rothenberg, Vice President, PTPN, dated August 11, 2008 on the issue of proposed section 9792.24.3(b)(1), above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	limit after the 6-month postsurgical physical medicine period, whether that mean that the injured worker is not entitled to an additional 24 visits beyond what they already received?			
9792.24.3(b)(1)	Commenter objects to reverting back to any unused pre-surgical visits after the postsurgical period without demonstrating the potential for further functional improvement.	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** See response to Nancy Rothenberg, Vice President, PTPN, dated August 11, 2008 on the issue of proposed section 9792.24.3(b)(1), above. Moreover, it is noted that the injured worker may still have further medical care needs and may consume the remaining visits from the 24-visit cap.	None.
9792.24.3(b)(1)	Commenter states that there are no studies to support a need to change the CPT's 90 day follow-up period for major surgeries. The CPT's 90 day follow–up period is accepted by the AMA, CMS and the OMFS and is considered a sufficient period to cover typical postoperative care related to a major surgery. Commenter indicates that for these reasons, CWCI recommends replacing references to the "postsurgical physical medicine period" with "90 day follow-up period." Commenter recommends that the language in § 9792.24.3(b)(1) be amended as follows: "The postsurgical treatment guidelines apply to visits during the 90 day follow-up ~~postsurgical physical medicine~~ period after surgery only ~~and to surgeries as defined in these guidelines~~. At the conclusion of the 90 day follow-up ~~postsurgical physical medicine~~ period, treatment reverts back to the applicable 24-visit limitation for chiropractic, occupational and physical therapy pursuant to Labor Code section 4604.5(d)(1)."	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** DWC **disagrees** with the commenter's recommendation of using a 90-day follow-up period. As indicated in the ISOR, the postsurgical physical medicine period was defined because it was not provided for in the Current Procedural Terminology 2008 (CPT 2008). The CPT 2008 sets forth surgery guidelines, and refers to a "CPT Surgical Package Definition." (CPT 2008, p. 47) The CPT surgical package definition encompasses all care directly provided as part of any surgery. It involves "[t]ypical postoperative follow-up care" (CPT 2008, p. 47) however, it does not discuss postoperative physical medicine or the period of time needed to achieve postsurgical physical medicine goals. "The services provided by a physician to any patient by their very nature are	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			variable." (CPT 2008, p. 47) The postsurgical package concept contains items that occur with every surgery. The ISOR indicated that it is important to note that physical medicine is not needed following every surgery. For this reason, physical medicine is not included in the postsurgical package concept. The guidelines define the "postsurgical physical medicine period" as the time frame that is needed for postsurgical treatment, beginning with the date of the procedure and ending at the time specified for the specific surgery, in the postsurgical physical medicine treatment recommendations set forth in subdivision (d) of this section. For this reason, proposed section 9792.24.3(d) sets forth the postsurgical physical medicine recommendations, which indicates the expected frequency and duration of therapy specific to the type of surgery performed. During the healing process, there is also variability such that some patients require no physical medicine and other patients require intensive efforts to restore function with physical medicine. The ISOR further indicated that following each surgery there is a time interval where physical medicine can be provided to restore optimal form and function. The time	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			intervals will depend on the nature of the surgery and the patient.	
9792.24.3(c)(1)	Commenter states that section 9792.24.3(c)(1) contains a comma after the phrase "nurse practitioner." Commenter opines that with the comma the section appears to state that a nurse practitioner would not need to be working with a physician which would be an expansion of the nurse practitioner's current scope of practice. Commenter recommends that the comma be removed.	Tim Madden Written & Oral July 2, 2008 August 12, 2008	**Agree.** The intention of the Subdivision 9792.24.3(c)(1) is to have the nurse work with the surgeon as part of the surgical team. The comma is removed to avoid misinterpretation of this provision. This language is also consistent with the language set forth in subdivision 9792.24.3(c)(5)(A).	**Subdivision 9792.24.3(c)(1)** is corrected for clarification purposes to delete the comma after the phrase "a nurse practitioner."
9792.24.3(c)(1)	Commenter is concerned with removing patient management from the primary treating physician. Commenter believes that the surgeon and the primary treating physician should discuss treatment and that the primary treating physician should submit the request, as with all other types of requests from secondary providers. Commenter states that claims administrators are trained to be vigilant about watching for Requests for Authorization via the PR-2. Commenter indicates that with the surgeon sending the Request for Authorization in on virtually any document, it could easily be missed, creating a lag in the authorization and treatment for the patient. Commenter cites Tit. 8 C.C.R. Sec. 9785 (a) (4), stating that it indicates that it is the Primary Treating Physician who is responsible for the "scope and extent of the employee's continuing medical treatment." Commenter cites subdivision (b) (1) of the same section, which states that, "An employee shall have no more than one Primary Treating Physician at a time."	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** DWC **disagrees** with the comment. Surgery requires specialized care and the treatment must be directed by the surgeon. If the surgeon is not the primary treating physician, the treatment is delegated to the surgeon by referral. Through referral and because of the delegation of this treatment, the surgeon can make decisions independently that pertain to the surgical and postsurgical care. Some surgeons use other physicians to assist during the postoperative course. Therefore, physicians designated by that surgeon can manage the postoperative rehabilitation. This does not affect the reporting requirements of the treating physician as the surgeon would report to the primary treating physician. DWC is in the process of revising the Primary Treating Physician Reporting Requirement regulations and this regulatory area	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			will be further clarified in the near future.	
9792.24.3(c)(1)	Commenter recommends that section 9792.24.3(c)(1) be deleted. Commenter states that this paragraph is unnecessary given the changes recommended by CWCI. Commenter further states that the regulation cannot say that "only the surgeon who performed the operation, a nurse practitioner, or physician assistant working with the surgeon, or a physician designated by that surgeon can make a determination of medical necessity because the statutes do not give the presumption of correctness to any of these medical providers; nor can it restrict prescriptions for postsurgical treatment to those providers. Commenter adds that Labor Code § 4061.5 requires the treating physician primarily responsible for managing the care of the injured worker (the primary treating physician) or a designated physician to "render opinions on all medical issues necessary to determine eligibility for compensation." Commenter also adds that Labor Code sections 4603.2 and 4603.4 allow for payment for "medical treatment provided or authorized by the treating physician selected by the employee or designated by the employer" (the primary treating physician). Commenter argues that if the paragraph is not deleted, the language must be modified to comply with these Labor Code sections.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree**. See response to Steven Suchil, Assistant Vice President, American Insurance Association, dated August 12, 2008 on the issue of section 9792.24.3(c)(1), above.	None.
9792.24.3(c)(2)	Commenter recommends that 9792.24.3(c)(2) be deleted. Commenter opines that § 9792.24.3(c)(2) is not necessary because such considerations are routine when prescribing or requesting medical treatment. Commenter states that a specific statement would only be appropriate if an exception is being created.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** DWC **disagrees** with the recommendation that section 9792.24.3(c)(2) be deleted. DWC believes that it is appropriate to specify "[t]he medical necessity for postsurgical physical medicine treatment for any given patient is dependent on, but not limited to, such factors as the comorbid medical conditions; prior pathology and/or surgery involving	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			same body part; nature, number and complexities of surgical procedure(s) undertaken; presence of surgical complications; and the patient's essential work functions." Addressing these factors in the proposed regulations alerts the regulated public that in some cases, therapy may not be necessary and in other cases, there may be a need for more therapy. The information contained in this section is useful for utilization review to determine intensity and appropriateness, and duration of treatment.	
9792.24.3(c)(3)	Commenter suggests the following modifications to 9792.24.3(c)(3), arguing that this simplified procedure is appropriate within the 90 day follow-up period: "If postsurgical physical medicine is medically necessary, an initial course of therapy may be prescribed. If it is determined that additional functional improvement can be accomplished, and ~~W~~with documentation of functional improvement, ~~a~~ subsequent ~~course of~~ therapy may be prescribed within the ~~paramerter of the general course of therapy applicable to the specific surgery~~ follow-up period after surgery. ~~If it is determined that additional functional improvement can be accomplished after completion of the general course of therapy, physical medicine treatment may be continued up to the end of the postsurgical physical medicine period.~~"	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** See response to comment submitted by same commenter on section 9792.24.3(b)(1).	None.
9792.24.3(c)(3)	Commenter repeats her comments from the initial adoption of the MTUS regarding the general requirement that "functional improvement" must be shown in order to authorize continued treatment. Commenter states that proposed §9792.24.3(c)(3) provides that an initial course of medically necessary	Sue Borg, President California Applicants' Attorneys Association Written & Oral	**Disagree.** DWC **disagrees** with the comment. Commenter does not provide scientific evidence to show that continued therapy is necessary to maintain an individual's functional level. It is expected that	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	postsurgical physical therapy may be prescribed, and that additional therapy may be prescribed upon documentation of functional improvement. Commenter adds that the statutory mandate in Labor Code §4600 is the provision of treatment "that is reasonably required to cure *or relieve* the injured worker. ..." Commenter states that unfortunately, for some workers "functional improvement" may not be possible, but continued treatment may prevent a deterioration of their physical condition. Commenter states that functional improvement should be a goal in most cases, but in some cases merely maintaining the current level of functional capacity requires continuing treatment.	August 12, 2008	with successful rehabilitation an injured worker can continue his or her self-care program. Dependency is not a desired health outcome. In terms of post surgical therapy, providing relief to the injured worker, applies only during the postsurgical interval and continued care beyond the interval would fall under the chronic pain guidelines. Moreover, there is no need to change the definition of functional improvement. It is anticipated that ultimately a functional plateau is reached, at which point a chronic care plan may be appropriate (see chronic pain medical treatment guideline introduction). Treatment when a functional plateau is reached is beyond the scope of the post surgical guidelines.	
9792.24.3(c)(4)(A)	Commenter recommends modification to § 9792.24.3(c)(4)(A) as follows: "In the event the patient sustains an exacerbation related to the procedure performed after postsurgical physical medicine treatment has been discontinued and it is determined that more visits are medically necessary, physical medicine treatment shall be provided within the 90 day follow-up ~~postsurgical physical medicine~~ period." Commenter opines that adding "postsurgical physical medicine" clarifies which treatment has been discontinued.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	See response to comment submitted by same commenter on section 9792.24.3(b)(1).	None.
9792.24.3(c)(4)(A)	Commenter states that she recognizes that proposed §9792.24.3(c)(4)(A) allows additional treatment	Sue Borg, President California	**Disagree.** See response to comment submitted by same	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	where the worker sustains an "exacerbation." Commenter states that, however, to require that the worker actually experience this "exacerbation" before authorizing added treatment, when clinical evidence indicates that discontinuation of the treatment will lead to deterioration of the worker's condition, is both harmful to the worker and wasteful to the system. Commenter repeats her recommendation that the definition of "functional improvement" be amended to provide that it also encompasses those situations where continued treatment is necessary to maintain the worker's current functional capacity and/or to prevent deterioration of the worker's condition.	Applicants' Attorneys Association Written & Oral August 12, 2008	commenter on section 9792.24.3(c)(3), above.	
9792.24.3(c)(4)(A)	Commenter states that §9792.24.3(c)(4)(A) contradicts the language in § 9792.24.3(b)(1) by stating that an injured worker receiving additional treatment after exacerbating the surgery site would be allowed to start up the postsurgical physical medicine period again even if discharged, within the six month postsurgical physical medicine period.	Tameka Island, Executive Associate California Physical Therapy Association August 12, 2008	**Disagree.** Commenter interprets this section by stating that "§9792.24.3(c)(4)(A) contradicts the language in § 9792.24.3(b)(1) by stating that an injured worker receiving additional treatment after exacerbating the surgery site would be allowed to start up the postsurgical physical medicine period again, even if discharged, within the six month postsurgical physical medicine period." Commenter's interpretation of this section is incorrect. The postsurgical period does not start up again after an exacerbation. Rather, more therapy can be done within the originally defined postsurgical period.	None.
9792.24.3(c)(4)(A)	Commenter states that § 9792.24.3 (c)(4)(A) speaks to a patient receiving additional treatment after exacerbating the surgery site. Commenter states that the language of this section would allow the injured worker to start up the postsurgical physical medicine	Nancy Rothenberg, Vice President PTPN August 11, 2008	**Disagree.** See response to comment submitted by Tameka Island, Executive Associate, California Physical Therapy Association, dated August 12,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	period again even if discharged, within the six month postsurgical physical medicine period. Commenter questions how many visits are allowed at this point? Commenter suggests that perhaps a table of time periods and visit allowances is called for to clarify the regulations?		2008, on proposed Section 9792.24.3(c)(4)(A). This section is clear that the treatment being provided for exacerbation related to the procedure "shall be provided within the postsurgical physical medicine period."	
9792.24.3(c)(4)(B)	Commenter recommends that § 9792.24.3(c)(4)(B) be amended as follows: "In cases where no functional improvement is demonstrated, postsurgical treatment shall be discontinued at any time during the ~~postsurgical physical medicine~~ follow-up period."	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, on Section 9792.24.3(b)(1), above.	None.
9792.24.3(c)(4)(B)	Commenter recommends the following change for the sake of brevity and greater clarity in § 9792.24.3(c)(4)(B): "In cases where no functional improvement is demonstrated, postsurgical treatment shall be discontinued." ~~at any time during the postsurgical physical medicine period"~~	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** DWC believes that for clarity purposes it is best to specify the interval (e.g., the postsurgical physical medicine period) during which functional improvement has to be demonstrated. It is noted that postsurgical treatment is an exception to the cap, i.e., the postsurgical period, and treatment pursuant to postsurgical treatment determinations matter only within this time period.	None.
9792.24.3(c)(5)	Commenter recommends that § 9792.24.3(c)(5) be amended as follows: "Postsurgical physical medicine t~~T~~reatment is provided to patients to facilitate postsurgical functional improvement."	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** Commenter's proposed changes are not accepted for the reasons set forth in connection with the response to the same commenter on section 9792.24.3(a) above.	None.
9792.24.3(c)(5)(A)	Commenter recommends replacing the phrase "or physician designated by that surgeon" with the phrase "the primary treating physician." Commenter opines that her change is necessary because the primary treating physician has responsibility for authorizing	Brenda Ramirez, Claims and Medical Director California Workers' Compensation	**Disagree.** See response to comment submitted by Steven Suchil, Assistant Vice President, American Insurance Association, dated August 12, 2008, on section	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the medical treatment plan as discussed in (c)(1). Commenter also recommends replacing the word "should" with the word "shall" to ensure injured employees will receive these superior medical practices for optimum recovery and return to work. Thus, commenter's changes are recommended as follows: "The surgeon who performed the operation, a nurse practitioner or physician assistant working with the surgeon, ~~or physician designated by that surgeon~~ the primary treating physician, the therapist, and the patient ~~should~~ shall establish quantifiable, functional goals achievable within a specified timeframe."	Institute August 12, 2008	9792.24.3(c)(1), above. Moreover, **disagree** with the suggestion substituting the word "should" with the word "shall" as each case needs to be evaluated individually. Although it is preferable that quantifiable functional goals be defined, depending on case variables, each case will require an individualized approach and therefore some discretion must be left to the therapist and postsurgical team. Because it is necessary to report functional improvement, functional goals are implicit when demonstration of function improvement is required to continue therapy. Thus, it is not necessary to use the word "shall" in each case.	
9792.24.3(c)(5)(A)	Commenter recommends that section 9792.24.3(c)(5)(A) be amended as provided below. Commenter states that without these "quantifiable, functional goals" being required, demonstrating functional improvement is difficult, if not impossible and can be expected to lead to disputes. Thus, commenter's changes are recommended as follows: "The surgeon who performed the operation, a nurse practitioner or physician assistant working with the surgeon, or physician designated by that surgeon, the therapist, and the patient ~~should~~ shall establish quantifiable, functional goals achievable within a specified timeframe."	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, on section 9792.24.3(c)(5)(A), above.	None.
9792.24.3(c)(5)(A)	Commenter states that **§9792.24.3 (c)(5)(A)** uses the expression "should" and "allows". The CPTA	Tameka Island, Executive Associate	**Disagree.** See response to comment submitted by Brenda	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	requests that the DWC consider the use of these words as suggestive and not prescriptive.	California Physical Therapy Association August 12, 2008	Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, on section 9792.24.3(c)(5)(A), above.	
9792.24.3(c)(5)(A)	Commenter states that section 9792.24.3(c)(5)(A) on page 13 uses the words "should" and "allows." Commenter questions does the DWC consider the use of this word prescriptive or suggestive? Commenter notes that the word "should" is used multiple times throughout the proposed language.	Richard Katz California Physical Therapy Association August 11, 2008 Oral Comment	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, on section 9792.24.3(c)(5)(A), above.	None.
9792.24.3(c)(5)(B)	Commenter also recommends replacing the word "should" with the word "shall" in § 9792.24.3(c)(5)(B) to ensure injured employees will receive these superior medical practices for optimum recovery and return to work. Thus, commenter's changes are recommended as follows: "Patient education regarding postsurgical precautions, home exercises, and self-management of symptoms shall ~~should~~ be ongoing components of treatment starting with the first visit. Intervention shall ~~should~~ include a home exercise program to supplement therapy visits.	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** See response to comment submitted by same commenter, on Section 9792.24.3(c)(5)(A), above. DWC agrees that it is preferable that home program be instituted depending on case variables, as each case will require separate assessment for when the home program should begin. If the patient is making a rapid recovery, a formal home program may not be necessary. Additionally, other members of the surgical team besides the therapist may provide home care instructions	None.
9792.24.3(c)(5)(B)	Commenter believes education and home exercises should also be a mandate rather than via the permissive "should." Commenter states that this opinion is also contained in the proposed Chronic Pain Guideline. (Commenter makes reference to Section II Physical Medicine.) Commenter states that this subdivision should be amended as follows: "Patient education regarding postsurgical precautions, home exercises, and self-management of symptoms	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, on 9792.24.3(c)(5)(B), above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	~~should~~ shall be ongoing components of treatment starting with the first visit. Intervention ~~should~~ shall include a home exercise program to supplement therapy visits."			
9792.24.3(c)(5)(C)	Commenter also recommends replacing the word "should" with the word "shall" in § 9792.24.3(c)(5)(C) to ensure injured employees will receive these superior medical practices for optimum recovery and return to work. Thus, commenter's changes are recommended as follows: "Modalities (CPT codes 97010 through 97039) shall only be performed in conjunction with other active treatments. Although these modalities are occasionally useful in the post surgical physical medicine period, their use ~~should~~ shall be minimized in favor of active physical rehabilitation and independent self management."	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree. Disagree** with the suggestion substituting the word "should" with the word "shall" as each case needs to be evaluated individually. Although it is preferable that modalities should be minimized, depending on case variables, each case will require separate assessment for the medical necessity for active vs. passive treatments in the post operative interval. If functional improvement is not reported, then there will be no justification for continued therapy.	None.
9792.24.3(c)(5)(C)	Commenter recommends the following change in order to make this subsection comply with the Ground Rules in the Official Medical Fee Schedule and current thinking in the medical world, which believes active procedures to have a significantly greater benefit to the passive modalities. Commenter states that this is also espoused in Section II of the proposed Chronic Pain Guideline under Physical Medicine. Thus, commenter's changes are recommended as follows: "Modalities (CPT codes 97010 through 97039) ~~should~~ shall only be performed in conjunction with other active treatments. Although these modalities are occasionally useful in the post surgical physical medicine period, their use should be minimized in favor of active physical rehabilitation and independent self-management."	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, dated August 12, 2008, on section 9792.24.3(c)(5)(C), above.	None.
9792.24.3(d)(1)	Commenter makes reference to § 9792.24.3(d)(1), and	Brenda Ramirez,	**Disagree. Disagree** with	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	states "See the discussion in the introductory recommendations." Commenter recommends that § 9792.24.3(d)(1) be amended as follows: "~~The postsurgical physical medicine treatment recommendations, as listed below, indicate frequency and duration of postsurgical treatment for specific surgeries. The specified surgeries in these guidelines are not all inclusive.~~ Postsurgical physical medicine and rehabilitation services shall be provided in accordance with the clinical topic sections 9792.23.1 through 9792.24 without regard to 24 visit limitations imposed on injuries sustained after 2003 by Labor Code section 4604.5(d)(1). Requests for additional postsurgical physical medicine treatment ~~not included in these guidelines~~ shall be considered pursuant to section 9792.25." ~~9792.21(e)~~. ~~The physical medicine treatment recommendations (listed alphabetically) are adapted from the Official Disability Guidelines (ODG) except where developed by the Division of Workers' Compensation and indicated as "[DWC]." The postsurgical physical medicine period is identified by an asterisk [*] as developed by DWC. A copy of citations listed in the postsurgical treatment guidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov.~~	Claims and Medical Director California Workers' Compensation Institute August 12, 2008	commenter's edits to section 9792.24.3(d)(1). The clinical topics sections do not cover post surgical treatment and therefore cannot be used for postsurgical treatment guidelines.	
9792.24.3(d)(1)	Commenter states that Labor Code section 4604.5 (d)(3) requires a postsurgical treatment schedule to conform to Labor Code section 5307.27, which directs the schedule to address, "at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases." Commenter argues that the Administrative Director has attempted to address frequency and duration of physical medicine for each diagnosis. Commenter	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Agree in part. Disagree** with the comment that the postsurgical treatment guidelines do not comply with the requirements of the statute because they do not address "all treatment procedures and modalities commonly performed in workers' compensation cases" pursuant to Labor Code section 5307.27. The postsurgical	The following section has been added to the proposed regulations: **Section 9792.24.3(d)(2):** "(2) Appendix C—Postsurgical Treatment Guidelines Evidence-Based Reviews—is incorporated by

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	opines that this is not what the statute requires. Commenter states that the statute requires the schedule to address the frequency, duration, intensity, and appropriateness of all treatment **procedures and modalities**. Commenter states that physical medicine is the treatment **type**. Commenter adds that physical medicine procedures and modalities are listed in the physical medicine section of the Official Medical Fee Schedule (OMFS). Commenter points out that again, the problem is that there are no studies on which to address the physical medicine procedures and modalities. Commenter opines that the Administrative Director cannot create a compliant schedule and commenter believes therefore that the Administrative Director should not adopt the proposed postsurgical treatment schedule. Commenter states that if, however, the Administrative Director decides to move forward with recommendations on physical medicine visits and durations in the absence of supporting studies on postsurgical physical medicine, Commenter offers the specific recommendations: • "Commenter states that using OMFS descriptors and OMFS codes will eliminate confusion and disputes over which surgeries are intended. Commenter recommends that the DWC replace the body parts and diagnoses under the "postsurgical Treatment Guidelines" with surgeries using OMFS descriptors and OMFS codes." • "Commenter states that the statute requires the schedule to address the frequency, duration, intensity, and appropriateness of all treatment **procedures and modalities**. Commenter recommends that to the extent possible, DWC add OMFS codes and descriptors for physical medicine		treatment guidelines address procedures and modalities as required by the statute. Section 9792.24.3(c)(5)(B) addresses procedures such as patient education for instructions regarding home exercise, and self-management of symptoms. Moreover, modalities are addressed in Section 9792.24.3(c)(5)(C), wherein it is specified that modalities are occasionally useful in the postsurgical physical medicine period, and that their use should be minimized in favor of active physical rehabilitation and independent self-management. **Disagree** with the suggestion that the OMFS descriptors and OMFS codes be used for surgeries and physical medicine procedures and modalities in the guidelines. DWC believes that the use of OMFS CPT Codes and descriptors for surgeries and physical medicine procedures and modalities is overly restrictive and does not clearly communicate the types of surgeries the patient received. **Disagree** with the suggestion that the "postsurgical physical medicine period" be replaced with a "90 day follow-up period." In the ISOR, DWC stated at p. 47 as follows:	reference into the MTUS as supplemental part of the Postsurgical Treatment Guidelines. A copy of Appendix C may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov"

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	procedure and modalities." • "Commenter makes reference to the discussion for §9792.24.3(b)(1) above, and recommends that DWC replace the phrase "postsurgical physical medicine treatment period" with the phrase "90 day follow-up period" and remove the listed periods." • "Commenter states that the ODG "ratings" do not comply with the MTUS standards and should be replaced by MTUS ratings. Commenter opines that if they remain, an explanation will be necessary so that all parties can understand their meaning. Commenter recommends that DWC replace the ODG "ratings" in Appendix E with MTUS ratings. Commenter suggests if the Administrative Director decides to retain them, add an explanation of the ODG rating methodology." • "Commenter states that appendices with information on medical evidence relied upon should be part of the regulation so that parties can compare other medical evidence when considering alternate treatment. Commenter suggests that the Appendices be added to the regulations by reference."		"It is necessary to define the postsurgical physical medicine period as it is not provided for in the Current Procedural Terminology 2008 (CPT 2008). The CPT 2008 sets forth surgery guidelines, and refers to a "CPT Surgical Package Definition." (CPT 2008, p. 47.) The CPT surgical package definition encompasses all care directly provided as part of any surgery. It involves "[t]ypical postoperative follow-up care" (CPT 2008, p. 47), however, it does not discuss postoperative physical medicine or the period of time needed to achieve postsurgical physical medicine goals. "The services provided by a physician to any patient by their very nature are variable." (CPT 2008, p. 47) The postsurgical package concept contains items that occur with every surgery. It is important to note that physical medicine is not needed following every surgery. For this reason, physical medicine is not included in the postsurgical package concept. These guidelines define the "postsurgical physical medicine period" as the time frame that is needed for postsurgical treatment, beginning with the date of the procedure and ending at the time specified for the specific surgery, in the postsurgical	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			physical medicine treatment recommendations set forth in subdivision (d) of this section. Proposed section 9792.24.3(d) sets forth the postsurgical physical medicine recommendations, which indicates the expected frequency and duration of therapy specific to the type of surgery performed. During the healing process, there is also variability such that some patients require no physical medicine and other patients require intensive efforts to restore function with physical medicine. Following each surgery there is a time interval where physical medicine can be provided to restore optimal form and function. The time intervals will depend on the nature of the surgery and the patient." DWC believes that it provided sufficient explanation in its ISOR, for the reasons for the "postsurgical physical medicine period." **Disagree** with regard to commenter's suggestion regarding ODG's ratings**.** See response to same commenter on the issue of proposed section 9792.25(c)(1), below. **Agree** that the evidence-based reviews as reflected in Appendix C—Postsurgical Treatment Guidelines, Evidence-Based	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Reviews, should be incorporated into the MTUS. The Evidence-Based Reviews will be incorporated into the MTUS in proposed section 9792.24.3(d)(2).	
9792.24.3(d)(1)	Commenter believes that the individual procedures in the Post-Surgical Treatment Guideline should have the Strength of Evidence rating included here as part of the regulation, so that they are evident to the regulated community and the WCAB. Commenter notes that in the Initial Statement of Reasons Appendix C that each and every procedure is marked with an ACOEM Strength of Evidence score of 1 and with the following "No Evidence Based Reviews Conducted" or "There were no studies on the need for post-surgical physical medicine." Commenter states that it is difficult to understand how this being the case, [when] these quite generous levels of therapy are being proposed as scientifically and evidence-based, peer reviewed and meeting a nationally recognized standard.	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Agree in part. Agree** that the evidence-based reviews as reflected in Appendix C—Postsurgical Treatment Guidelines, Evidence-Based Reviews, should be incorporated into the MTUS. The will be incorporated into the MTUS in proposed section 9792.24.3(d)(2). **Disagree** with the comment that the postsurgical medical treatment guidelines do not meet the requirements of the statute. See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3, above.	The following section has been added to the proposed regulations: **Section 9792.24.3(d)(2):** "(2) Appendix C—Postsurgical Treatment Guidelines Evidence-Based Reviews—is incorporated by reference into the MTUS as supplemental part of the Postsurgical Treatment Guidelines. A copy of Appendix C may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov."
9792.24.3(d)(1)	Commenter states that he is a practicing hand surgeon in the Van Nuys community, president of the California Society Industrial Medicine and Surgery, and also represents the board of the California Orthopaedic Association. Commenter indicates that DWC has received the letter from the California Orthopaedic Association stating that that organization is basically in support of the postoperative treatment guides as written; however, they have some concerns. Commenter states that one concern is that the interpretation not be that these are caps but guidelines	George W. Balfour, M.D., President California Society Industrial Medicine and Surgery, California Orthopaedic Association, Oral Comment August 11, 2008 Written Comment	**Disagree.** Commenter expresses the concern "that the interpretation not be that these are caps but guidelines for the utilization of various diagnoses." DWC notes that in fact, the post surgery period defines the interval when the postsurgical treatment guidelines apply, thus limiting the duration of treatment. During the interval, the amount of therapy any one injured	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	for the utilization of various diagnoses. Commenter states that they are concerned that consideration be made for co-morbidities such as diabetes or age which might require greater utilization. Commenter states that they would encourage the language such that the tendency of the utilization review physicians not be the selection of a lowest available guide which goes on but rather demonstrates the greatest needs of the patient.	June 29, 2008	worker receives after surgery will depend on the particulars of each case. Some cases require more therapy while others require less therapy. Commenter also indicates that he is concerned that consideration be made for co-morbidities such as diabetes or age which might require greater utilization. It is noted that the guidelines already include language specifying that these patient variables need to be accounted for in the guidelines. They are contained in section 9792.24.3(c)(2), and state: "The medical necessity for postsurgical physical medicine treatment for any given patient is dependent on, but not limited to, such factors as the comorbid medical conditions; prior pathology and/or surgery involving same body part; nature, number and complexities of surgical procedure(s) undertaken; presence of surgical complications; and the patient's essential work functions."	
9792.24.3(d)(1) Carpal Tunnel Syndrome	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the Carpal Tunnel Syndrome postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be included.	Shawn Phipps, President Occupational Therapy Association of California August 8, 2008	**Disagree.** Commenter states that the term "physical therapy" is used in connection with the specific postsurgical physical medicine guideline. This is incorrect. The guideline uses the correct terminology of "physical medicine."	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.3(d)(1) Carpal Tunnel Syndrome	Commenter states that under the postsurgical treatment guidelines, specifically carpal tunnel syndrome, her association would like the language to be changed from "physical therapy" to "physical medicine" because occupational therapists play a very important role in rehab those patients and, therefore, I think we should be included in the guidelines.	Laura Lan Stewart, Occupational Therapy Association of California August 11, 2008 Oral Testimony	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Carpal Tunnel Syndrome	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the Carpal Tunnel Syndrome postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be included.	Charles Willmarth, Director, State Affairs and Reimbursement & Regulatory Policy The American Occupational Therapy Association, Inc. August 11, 2008	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Elbow & Upper Arm ECRB/ECRL debridement [DWC]	Commenter states that the guideline for Tennis elbow release setting forth 10 visits seems too low based on his clinical experience. Commenter states that DWC reports no published studies to support its guideline. Commenter states that he can make his cases and therapy records available. He indicates that he has a surgical Excel spreadsheet of his surgical cases going back to May of 1999. He believes that he releases 2-4 Tennis elbows a year. He believes his surgical Excel spreadsheet would be better than the zero studies DWC presently reports. Commenter further adds that alternatively DWC could contact the American Society for Surgery of the Hand for assistance. He indicates that they have a workers' compensation committee that might be willing to be of assistance.	George W. Balfour, M.D., President California Society Industrial Medicine and Surgery, California Orthopaedic Association, Oral Comment August 11, 2008 Written Comment June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3, above. Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute.	None.
9792.24.3(d)(1) Elbow & Upper Arm Ulnar nerve entrapment/Cubital tunnel syndrome	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the ulnar nerve entrapment/cubital tunnel syndrome postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be	Shawn Phipps, President Occupational Therapy Association of California August 8, 2008	**Disagree.** Commenter states that the term "physical therapy" is used in connection with the specific postsurgical physical medicine guideline. This is incorrect. The guideline uses the correct	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	included.		terminology of "physical medicine."	
9792.24.3(d)(1) Elbow & Upper Arm Ulnar nerve entrapment/Cubital tunnel syndrome	Commenter states that under the postsurgical treatment guidelines, specifically ulnar nerve entrapment, her association would like the language to be changed from "physical therapy" to "physical medicine" because occupational therapists play a very important role in rehab of those patients and, therefore, she thinks they should be included in the guidelines.	Laura Lan Stewart Occupational Therapy Association of California August 11, 2008 Oral Comment	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Elbow & Upper Arm Ulnar nerve entrapment/Cubital tunnel syndrome	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the ulnar nerve entrapment/cubital tunnel syndrome postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be included.	Charles Willmarth, Director, State Affairs and Reimbursement & Regulatory Policy The American Occupational Therapy Association, Inc. August 11, 2008	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Forearm, Wrist, & Hand Amputation of thumb, finger Amputation of fingers, Without replantation [DWC]	Commenter states that the guideline for finger amputations [without replantation] of 14 visits over 3 months appears low. He offers his surgical Excel spreadsheet of his surgical cases going back to May of 1999 for examination. In the alternative, he suggests that DWC could contact the American Society for Surgery of the Hand for assistance. He indicates that they have a workers' compensation committee that might be willing to be of assistance.	George W. Balfour, M.D., President California Society Industrial Medicine and Surgery, California Orthopaedic Association, Oral Comment August 11, 2008 Written Comment June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above. Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute.	None.
9792.24.3(d)(1) Forearm, Wrist, & Hand Extensor tendon repair or tenolysis [DWC]	Commenter states that the guidelines include the treatment for Finger extensor tenolysis with Finger extensor tendon repair. Commenter states that these are very different conditions. Commenter opines that a guideline of 14 visits for tendon repair is adequate, but not for tenolosys. Commenter suggests that a	George W. Balfour, M.D. June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	guideline of 25 visits for tenolysis is more adequate.		Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute.	
9792.24.3(d)(1) Forearm, Wrist, & Hand Ganglion and cyst of synovium, tendon, and bursa	Commenter states that in post ganglionectomy cases, some patients do not need much therapy. However, other patients get very stiff. He suggests a greater allowance, such as 20 visits, if significant loss of range of motion is documented.	George W. Balfour, M.D. June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above. Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute.	None.
9792.24.3(d)(1) Forearm, Wrist, & Hand PIP joint intraarticular fracture and or dislocation at proximal or middle phalanx [DWC]	Commenter opines that the guideline of 20 visits for PIP joint intraarticular fractures following surgery seems low for this difficult and slow-to-recover injury. He suggests a minimum of 30 visits. Commenter indicates that DWC included the basal joint in its search criteria for PIP joint studies. He believes that the basalar joint refers to the cm/c joint of the thumb.	George W. Balfour, M.D. June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above. Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute.	None.
9792.24.3(d)(1) Forearm, Wrist, & Hand TFCC injuries-debridement (arthroscopic) [DWC]	Commenter opines that diagnostic arthroscopy without debridement or repair requires little post surgical therapy. However, TFCC debridement requires more than the 10 visits as set forth in the guideline. He would suggest 20 visits. Commenter also states that TFCC repairs, where the structure was sutured to the capsule of the wrist and held in a case take ever more therapy. Commenter offers his surgical Excel spreadsheet of his surgical cases going back to May of 1999 for examination. In the alternative, he suggests that DWC could contact the American Society for Surgery of the Hand for assistance. He indicates that they have a	George W. Balfour, M.D. June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above. Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	workers' compensation committee that might be willing to be of assistance.			
9792.24.3(d)(1) Forearm, Wrist, & Hand	Commenter indicates that the guidelines make no mention of intraarticular fractures of the elbow. He states that the elbow is a problem joint with a great tendency to stiffness. He suggests a guideline of 30 visits. Commenter offers his surgical Excel spreadsheet of his surgical cases going back to May of 1999 for examination. In the alternative, he suggests that DWC could contact the American Society for Surgery of the Hand for assistance. He indicates that they have a workers' compensation committee that might be willing to be of assistance.	George W. Balfour, M.D. June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above. Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute. In order to add a new surgery to the guidelines, this would require a new rulemaking to conduct a new evidence-based review. The surgery will be considered when the regulations are revised.	None.
9792.24.3(d)(1) Head	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the head postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be included.	Shawn Phipps, President Occupational Therapy Association of California August 8, 2008	**Disagree.** Commenter states that the term "physical therapy" is used in connection with the specific postsurgical physical medicine guideline. This is incorrect. The guideline uses the correct terminology of "physical medicine."	None.
9792.24.3(d)(1) Head	Commenter states that under the postsurgical treatment guidelines, specifically head injuries, her association would like the language to be changed from "physical therapy" to "physical medicine" because occupational therapists play a very important role in rehab of those patients and, therefore, commenter thinks they should be included in the guidelines.	Laura Lan Stewart. Occupational Therapy Association of California August 11, 2008 Oral Comment	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Head	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the head postsurgical treatment guideline as occupational therapists have played a	Charles Willmarth, Director, State Affairs and Reimbursement &	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	critical role in the treatment of this condition and should therefore be included.	Regulatory Policy The American Occupational Therapy Association, Inc. August 11, 2008	dated August 8, 2008, above.	
9792.24.3(d)(1) Hip, Pelvis, Thigh (Femur)	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the hip, pelvis, thigh (femur) postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be included.	Shawn Phipps, President Occupational Therapy Association of California August 8, 2008	**Disagree.** Commenter states that the term "physical therapy" is used in connection with the specific postsurgical physical medicine guideline. This is incorrect. The guideline uses the correct terminology of "physical medicine."	None.
9792.24.3(d)(1) Hip, Pelvis, Thigh (Femur)	Commenter states that under the postsurgical treatment guidelines, specifically hip, pelvis and thigh, her association would like the language to be changed from "physical therapy" to "physical medicine" because occupational therapists play a very important role in rehab of those patients and, therefore, she thinks they should be included in the guidelines.	Laura Lan Stewart, Occupational Therapy Association of California August 11, 2008 Oral Comment	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Hip, Pelvis, Thigh (Femur)	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the hip, pelvis, thigh (femur) postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be included.	Charles Willmarth, Director, State Affairs and Reimbursement & Regulatory Policy The American Occupational Therapy Association, Inc. August 11, 2008	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Knee	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the knee postsurgical treatment guideline as occupational therapists have played a	Shawn Phipps, President Occupational Therapy Association	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	critical role in the treatment of this condition and should therefore be included.	of California August 8, 2008	dated August 8, 2008, above.	
9792.24.3(d)(1) Knee	Commenter states that under the postsurgical treatment guidelines, specifically knee, her association would like the language to be changed from "physical therapy" to "physical medicine" because occupational therapists play a very important role in rehab of those patients and, therefore, she thinks they should be included in the guidelines.	Laura Lan Stewart Occupational Therapy Association of California August 11, 2008 Oral Comment	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Knee	Commenter proposes that DWC change the language from "physical therapy" to "physical medicine treatment," in the knee postsurgical treatment guideline as occupational therapists have played a critical role in the treatment of this condition and should therefore be included.	Charles Willmarth, Director, State Affairs and Reimbursement & Regulatory Policy The American Occupational Therapy Association, Inc. August 11, 2008	**Disagree.** See response to comment submitted by Shawn Phipps, President, Occupational Therapy Association of California, dated August 8, 2008, above.	None.
9792.24.3(d)(1) Shoulder	Commenter opines that the guidelines should be generous for the shoulder. He believes that many patients take months of therapy and will not or cannot [do] it on their own.	George W. Balfour, M.D. June 29, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above. Moreover, anecdotal evidence or self-reported evidence does not meet the requirements of the statute.	None.
Appendix C—Postsurgical Treatment Guidelines (DWC 2008) Evidence-Based Reviews	Commenter states that in the case of post-operative physical therapy, there are evidence searches conducted by the DWC, concluding that there is insufficient evidence to make an evidenced-based recommendation. Commenter indicates that it is not clear whether these searches were done by modality or treatment as well as diagnosis or procedure. Commenter adds that if in fact there is little or no	Jeffrey S. Harris, M.D. August 11, 2008	**Disagree.** See response to comment submitted by California Workers' Compensation Institute, Brenda Ramirez, Claims and Medical Director, dated August 12, 2008, on section 9792.24.3 above. Specifically, the MEEAC and designated subject matter experts	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	evidence on which to base a recommendation, it would be important to specify whether the MEACC reached its own consensus on the number of post-operative PT visits or simply accepted the apparent opinion of the ODG authors and reviewers, who were not identified. Commenter indicates that there is no discussion of work conditioning or work hardening in this section. Commenter indicates that such programs can be helpful in rehabilitation if there is significant deconditioning or fear-avoidance behavior.		defined the postsurgical physical medicine period for the specified surgeries. With regard to work-hardening and conditioning, these may not be appropriate in the immediate postsurgical interval as tissue healing is occurring although in selected cases, it might be appropriate after completion of the post-surgical period. It is noted that the October 23, 2008 ODG revised chronic pain guidelines now includes Work Hardening.	
9792.25(c)(1) Grading Methodology	Commenter states that the proposed chronic pain medical treatment guidelines are not evaluated according to the rating criteria and strength of evidence standards in section 9792.25(c)(B) as required in section 9792.26(c) of these regulations. Commenter further states that section 9792.26(c)(3) requires the members of the medical evidence evaluation advisory committee to "Apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where a guideline is developed by the Administrative Director…" Commenter indicates that the hierarchy of medical evidence - - the grading system that stratifies conservative, high quality research from the lower quality, less reliable case studies and anecdotes – is the backbone of the state's MTUS. Commenter adds that the hierarchy of medical evidence used in the proposed pain management guidelines, based largely on ODG, uses a more liberal hierarchy of medical evidence than the ACOEM standard of evidence. Commenter opines that, if adopted, the MTUS will be forced to combine dissimilar methods of grading medical evidence, a situation that can only lead to an	Brenda Ramirez, Claims and Medical Director California Workers' Compensation Institute August 12, 2008	**Disagree.** The substance of this section has not been changed in this rulemaking. The section is renumbered consistent with the internal reorganization of the MTUS. To clarify any confusion, the guidelines as contained in the MTUS are presumed to be correct. If a physician requests authorization for medical treatment which is not covered by the MTUS, that physician is required to rely on another guideline pursuant to § 9792.25(b), or provide scientific evidence using the strength of evidence as adopted from the ACOEM guidelines into the MTUS (§ 9792.25(c)). The strength of evidence is intended to overcome the presumption in the MTUS. As reflected in the regulations, the strength of evidence is used in situations where the treating physician is requesting (1) treatment not	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	increase in variation of medical treatment and a reduction in overall quality of care. A study [1 Harris, J., Ossler, C., Crane, R., Swedlow, A. Utilization Review & the Use of Medical Treatment Guidelines in California Workers' Compensation: A Comparison of ACOEM & AAOS on Medical Testing and Service Utilization. for Low Back Injury. CWCI Report to the Industry. February 2005] of a prior proposal to create a "patchwork" of disparate hierarchies and guidelines demonstrated the sub-optimal, unintended consequences of clinical and administrative "mixed signals." Commenter adds that if the Division decides to pursue adopting modified ODG guidelines on chronic pain, CWCI believes they must be evaluated prior to adoption using the study criteria and strength of evidence rating methodology in the regulations. The Division often relies on economic impact studies to model the likely impact of proposed regulatory change. Commenter adds that an economic impact analysis allows stakeholders the opportunity to plan for administrative and operational changes shaped by legislative and regulatory reform. Commenter adds that changes to the MTUS will affect underwriting, reserving, safety and health programs, medical management systems, vendor relationships, medical network panels, return-to-work programs and more. Commenter adds that after extensive consultation with the Division, CWCI believes such an economic impact analysis for the proposed chronic pain guidelines is not possible due to the conflict in evidence grading systems and lack of explicit recommendations. Commenter opines that without an objective financial impact analysis, the Division is taking a significant and unnecessary risk that can compromise the fundamental intent of the prior		addressed either in the MTUS or in other guidelines, (2) treatment recommendation at variance with the MTUS and other guidelines; and (3) treatment recommendation addressed in a guideline not included in the MTUS which is at variance with another guideline not included in the MTUS. Thus, the strength of evidence as adopted in § 9792.25(c) is not applicable to the DWC selection of guidelines to adopt into the MTUS. This is necessary because there is no consensus of a specific evidence rating system, and the ACOEM rating system is unique to ACOEM. If DWC were to only use ACOEM's rating system in its evaluation of guidelines to supplement the MTUS, DWC would be precluded from using any guidelines and would be limited solely to the ACOEM guidelines. To the contrary, the Labor Code allows for the use of other guidelines as Labor Code section 4604.5(e) provides that "for all injuries not covered by the … official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence-based medical treatment guidelines generally recognized by the national medical community and that are scientifically based."	

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	reforms to raise quality of care and lower the cost of health care delivery.		After DWC identifies a guideline to supplement the MTUS (Lab. Code, § 4604.5(e)), DWC, via the MEEAC, evaluates the guideline to identify areas which do not meet the requirements of the statute (§ 9792.26(c)(1).) In supplementing the guidelines, and in order to avoid internal conflict in the MTUS, DWC, via MEEAC, complies with the requirements of § 9792.26 (c)(2) and (c)(3) by applying the ACOEM's strength of evidence rating methodology to the scientific evidence. This is reflected in the evidence-based reviews conducted by the DWC, and reflected in Appendixes B and C. In terms of practical application, if a treating physician requests a treatment at variance with the MTUS, and provides scientific evidence to support that treatment such as a newly published randomized controlled study, utilization review (UR) will review the request and either agree or disagree with the treating physician's request. If a dispute arises, the issue will be resolved through the dispute resolution process pursuant to Labor Code section 4062, i.e., the process to resolve 4610 request for treatment issue which will be later presented to a worker's compensation	

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			administrative law judge for decision.	
9792.25(c)(1)	Commenter states that there are areas in which the methodology required by the MTUS regulations could be updated to conform to the actual state of the evidence base in the areas under consideration. Commenter offers the following bullet points in support of his comment: "• Commenter states that the MTUS strength of evidence rating system specifies that systematic reviews (SRs) or meta-analyses (MAs) support evidence grade A. Commenter states that the ACOEM strength of evidence ratings were adopted into the MTUS while still in draft as the best available system at the time. Commenter adds that since then, after exhaustive literature searches and evaluations of the quality of existing systematic reviews and meta-analyses in the areas germane to occupational medicine, SRs and MAs were deleted from the published ACOEM strength of evidence scheme as many SRs and MAs were found to be neither systematic nor accurate. • Commenter states that in many guidelines, studies other than randomized controlled trials are not used to support recommendations, as they are significantly less reproducible and more subject to bias."	Steven Suchil, Assistant Vice President American Insurance Association August 12, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.
9792.25(c)(1)	Commenter states that many WOEMA physician members provide care daily under the framework of the MTUS, and are particularly focused on the practical implementation of new chapters and any issues that would affect physicians working in the clinic or performing UR. Commenter indicates that specifically, his organization is concerned about the evaluation process for determining relative strength of evidence. Commenter states that ACOEM notes that the incorporation of the ODG-based chronic pain	Steven C. Schumann, M.D., Legislative Chair Western Occupational & Environmental Medicine Association, A Component Society of ACOEM	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.

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	chapter could inject ambiguity into the existing model in regulation for assessing evidence as the ODG-based chapter does not rely on a similar framework for evaluating evidence. Commenter states that for WOEMA, an additional concern stems from the language of 9792.23(b) and 9792.25, which denotes that any treatment not referenced in the listed guidelines can be supported through other scientifically valid, nationally-recognized standards. Commenter adds that if such guidelines do not exist, the regulations provide that treatment could be evaluated under ACOEM's strength of evidence rating methodology. Commenter sets forth the following questions: How are these determinations made? Who makes them? When provider and UR physician invoke different guidelines or evidence to support their decision to treat or deny, what is the exact process for determining which set of guidelines holds sway? And absent any guidelines, if provider and UR physician invoke different evidence, who determines which prevails? What if either the provider or UR physician disputes the decision? How are the normal UR timeframes affected by such a dispute? Commenter states that WOEMA believes that specific language should be added that addresses these questions. Commenter indicates that such clarification would make the MTUS regulations more useful to both provider and payers, who would have a clearer roadmap through the natural and inevitable areas of conflicting opinion. Commenter adds guidelines, based on original evaluation of evidence, rather than secondary evaluations contained in review articles, are inherently more valid and reliable and will ensure the quality outcomes the state hopes to achieve.	August 12, 2008 Written and Oral Testimony		
9792.25(c)(1)	Commenter is concerned regarding the use of	Advanced	**Disagree.** See response to	See Action taken in

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	ACOEM's evidence ranking scale. Commenter encourages the Department of Workers' Compensation to review comments regarding the use of ACOEM's evidence ranking scale, and consider those comments very carefully in making final determination on the proposed rules.	Neuromodulation Systems Barbara E. Raley, Senior Manager Strategic Health Policy and Reimbursement, August 12, 2008	comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above.	connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.
9792.25(c)(1)	Commenter believes that the combination of treatment recommendations authored by the Division and those adapted from ODG will cause potential confusion for providers and payers. Commenter states that the result of combining these guidelines is two completely different criteria for strength of evidence. Commenter notes that the recommendations authored by the Division follow the strength of evidence requirements of the MTUS contained in section 9792.22 (now proposed § 9792.25), including *Criteria Used to Rate Randomized Controlled Trials* and *Strength of Evidence Ratings*. Commenter adds that the recommendations adapted from ODG, however, use a proprietary rating system that is not consistent with section 9792.22 (now proposed § 9792.25). Commenter opines that lack of consistency with the requirements of section 9792.22 (now proposed § 9792.25) will raise problems for providers and payers.	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.
9792.25(c)(1)	Under the subtitle, ACOEM Strength of Evidence Rating Methodology, commenter states that currently, treatment guidelines are supposedly based on evidence. Commenter submits that nonetheless, the ACOEM Guidelines turn out to be based on consensus, not evidence. Commenter states that the issues of "evidence-based" modalities and "evidence of demonstrated efficacy" need further definition. Commenter states that some procedures with poor statistics may be immensely successful in some patients. Nonetheless, patients may be denied these treatments when insurance companies assert that such	Robert L. Weinmann, M.D. President, Union of American Physicians and Dentists Independent Practice Association August 12, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.

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	procedures are not "evidence based" and use this convenient phrase as a way to deny or delay care. Patients victimized by this technique may use up their temporary disability without ever getting the treatment they need. Commenter indicates that the Division of Workers Compensation should instruct claims administrators that it is wrongful conduct subject to penalty and fine to delay or deny a claim because the evidence relied upon to substantiate a request used methodology that was not or is not now within the Medical Treatment Utilization Schedule or MTUS or that conflicts with ACOEM.			
9792.25(c)(1)	Commenter reiterates his concern which was first submitted in December, 2006, regarding adoption of ACOEM's proprietary rating scale and methodology. Commenter quotes from his original comments as follows: "One of the critical issues facing the Division *(in its initial proposal of CCR Title 8, Section* 9792.2) was the fundamental conflict between the *ACOEM Guidelines* and Labor Code Section 5307.27. All treatment guidelines are mandated by statute to be evidence based. However, the ACOEM Guidelines were proven through an analysis provided to the Division by CSIMS, to be based in the majority on consensus. The Division's original proposal on listed consensus as a valid level of evidence." "ACOEM acknowledged the validity of this issue and responded by changing their method of evaluating evidence and the terminology used to describe it, by eliminating the phrase "consensus." By adopting ACOEM's revised "Strength of Evidence" scale, while apparently diffusing the fact that "consensus," (using the former terminology) could not be considered a level of evidence, the Division will now institutionalize a proprietary methodology as yet	Stephen J. Cattolica AdvoCal August 7, 2008 Oral Comment August 12, 1008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above. Moreover, DWC will consider commenter's suggestion that DWC adopt a different rating methodology which will be considered in future MTUS updates.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.

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	unpublished, unrecognized nationally and certainly not in wide use by other guideline authors. Setting aside the merits of the methodology, with this adoption, the Division places an undue burden on Utilization Review programs to compare ACOEM's current guidelines against all others that do not utilize the same evidentiary method and nomenclature. By adopting a proprietary criteria and method, the Division leaves treating physicians with very little chance to overcome the presumption of correctness, because no other guidelines have yet been developed using the same methods nor their evidentiary basis described in the same terms. Utilization Review programs will have no basis for comparison and thus approval of alternate treatment plans. Presuming that California's Schedule could set a precedent in this regard, California will force all other guidelines to adopt the same methodology in order to be considered for future inclusion into the Schedule. Thus the California Treatment Utilization Schedule will become permanently ensconced in the ACOEM system and perhaps forcing specialty societies and guideline authors to make a similar adoption, regardless of Division's intent or the need to expand it in the future." "We want to alert the Division that this apparent solution simply trades one conflict for another and will perhaps exacerbate debates and delays over requested treatment. If unchanged, it is most certain to increase conflict in the very near term after these regulations are finalized because the *ACOEM Guidelines, Second Edition,* are not translated into the new evidence scale." Commenter states that just as he stated more than 18 months ago, he believes it is inappropriate as a matter of public policy for the Division to adopt a proprietary			

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	"strength of evidence scale," which is not considered an industry standard or in widespread use by other entities which develop otherwise qualified, evidence based treatment guidelines. Commenter indicates that for example, ODG's "Explanation of Medical Literature Ratings," bears little resemblance to ACOEM's evidence scale or methodology. Commenter questions whether one is to infer, therefore, that the method used by ODG to evaluate evidence and any resulting recommendation, is inferior or simply defined in different terms? How does one compare the descriptions of the relative strength of evidence as presented by ODG with ACOEM's scale? Commenter states that the Division must provide guidance in this critical area; avert unwarranted conflicts and streamline numerous interactions. Commenter states that the interaction between a claims administrator and treating physician is one that may first come to mind, however, the second, almost more critical than the first, is the interaction between the judge, the applicant and the defendant in court when deciding a utilization review dispute and having no formal education or experience in the process of comparing disparate evidence based medical treatment guidelines. Commenter strongly urges the Division to address, in regulation, a procedure or approach that must be used when comparing the MTUS guidelines with other guidelines that may have been developed using other, valid, evidence evaluation scales and/or methodologies. Commenter requests that in addition, the Division instruct that claims administrators may not delay or deny a request for authorization solely because the evidence substantiating the request was originally evaluated using an evidence ranking scale and/or methodology other than that found within the			

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	MTUS.			
9792.25(c)(1)	Commenter indicates that his organization strongly directionally supports DWC's proposal that §9792.24.2 - Chronic Pain Medical Treatment Guideline replace Chapter 6 of the ACOEM Practice Guidelines, 2nd Edition (2004). Commenter states that his organization, however, has heard of some issues raised by physicians with whom they work regarding use of ACOEM's evidence ranking scale and encourage DWC to review and consider those comments carefully in making your final determination on the proposed rules.	Eric Hauth, Executive Director Neuromodulation Therapy Access Coalition August 12, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above. Moreover, DWC will consider commenter's suggestion that DWC adopt a different rating methodology which will be considered in future MTUS updates.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.
9792.25(c)(1)	Commenter states that although generally pleased with the proposed MTUS as drafted, CMA continues to have serious concerns with current regulations that do not recognize the authority of published consensus statements by nationally recognized specialties (Presumption of Correctness, Burden of Proof and Strength of Evidence section 9792.22, now proposed §9792.25). Commenter states that his organization understands and supports the need to give great weight to evidence-based medicine in the development of these guidelines. Commenter argues that nonetheless, some of the most important innovations in medicine are not always captured by strict evidence-based standards. Commenter states that there are several reasons for this, the most important of which is the widely recognized fact that there has not been research to establish evidence for the treatment of many conditions. Commenter indicates that given the absence of qualifying studies, especially in areas such as pain management, CMA believes it is imperative that some weight be given to published consensus statements by nationally recognized specialty societies. Commenter indicates that for these reasons, CMA urges the Division to	Frank D. Navarro, Associate Director, CES California Medical Association Written & Oral August 11, 2008 August 12, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above. Moreover, DWC will consider commenter's suggestion that DWC adopt a different rating methodology which will be considered in future MTUS updates.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.

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	consider taking either of the two following actions: Commenter suggests that option one would be to amend Table-B Strength of Evidence Ratings § 9792.22, to include language that recognizes published consensus statements by nationally recognized specialty societies. Commenter indicates that specifically, CMA would recommend the following additional language: *"(D) Level D. No research-based evidence, no RCTs. Published consensus statements by nationally recognized specialties exist."* Commenter suggests option two would be to adopt the Official Disability Guidelines (ODG) and its more robust methodology of ranking by type of evidence and ranking by quality within type of evidence, including ODG recommendations for these guidelines.			
9792.25(c)(1)	Commenter expresses significant concern regarding the use of ACOEM's evidence ranking scale. Commenter states that ACOEM's strength of evidence rating methodology is based largely - - if not exclusively - - on the randomized controlled trial (RCT). Commenter indicates that an 11-point scale is used to rate the quality of a randomized controlled trial as high (8-11 points), intermediate (4-7.5), or low (3.5 or less). Commenter states that while the RCT offers important advantages, such as providing a means of balancing known and unknown factors between groups, and ranks near the top of the evidence "pyramid", there are several other types of studies that can and should contribute to the body of evidence for a therapy – and constitute evidence in their own right but nonetheless appear to be dismissed by ACOEM. Commenter indicates that these include observational studies that may be in the form of a	N. William Fehrenbach, Director, State Government Affairs Medtronic August 10, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above. Moreover, DWC will consider commenter's suggestion that DWC adopt a different rating methodology which will be considered in future MTUS updates.	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.

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	case-control study, a cohort study, a prospective or retrospective case series, and others. Commenter adds that the expert medical opinion of physicians is often considered another level of evidence but appears not to be considered by ACOEM. Commenter indicates that ACOEM only considers RCTs and systematic reviews or meta-analyses thereby including only the "tip of the iceberg." Commenter adds that the ACOEM rating scale is rooted in the ability of the clinical study to blind patient and provider, which may not be possible for some device trials - - thereby inadvertently and unfairly misjudging the higher levels of implantable device evidence that do exist. Commenter also adds that as their analysis of the 2008 ACOEM Low Back and 2008 ACOEM Chronic Pain drafts demonstrate, while ACOEM evidence ranking system does not appear to consider "medical consensus opinion," a clear majority of "Recommendations" are based on evidence which is deemed to be "Insufficient" and by definition relies on "consensus." Commenter states that in strong contrast to ACOEM's ranking system, several other well-respected and widely-used methods for rating the strength of evidence for a single study and/or the body of evidence for a therapy do exist and should be considered. Commenter states though those alternatives may have their limitations regarding potentially failing to fully consider significant and unique challenges that one faces regarding the development and execution of device trials, these alternatives nonetheless are all significantly superior to ACOEM's evidence grading scale. Commenter encourages DWC to review the text, and the related appendix and consider choosing one of these approaches instead. Commenter offers the following options and text describing the options below: "Option 1: Oxford			

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	The Oxford Centre for Evidence-Based Medicine (OCEBM) was established in 1995 to develop, teach and promote evidence-based health care. They produce a bi-monthly journal, Evidence Based Medicine, in partnership with McMaster University and the British Medical Journal (BMJ). The Centre staff has published numerous articles and book chapters on evidence based medicine. OCEBM utilizes a Levels of Evidence document that considers all forms of evidence including systematic reviews, randomized controlled trials, cohort studies, outcomes research, case-control studies, case series, expert opinion and bench research. (http://www.cebm.net/)" "Option 2: ECRI ECRI Institute, a nonprofit organization which was established over 40 years ago, dedicates itself to using applied scientific research to understand which devices, drugs, and processes are best for patient care. They pride themselves in their unique ability to blend practical experience and uncompromising independence with thorough and objective evidence-based research. They are both a Collaborating Center of the World Health Organization (WHO) as well as an Evidence- Based Practice Center for the U.S. Agency for Healthcare Research and Quality (AHRQ). In conducting a health technology assessment, ECRI includes clinical studies of both prospective and retrospective design. Therefore, ECRIs internal validity scale and strength of evidence assessments allow for more than one type of study design to be included in their analysis. Recognizing that the methodological rigor of retrospective studies is typically lower than that of RCTs, ECRI does state that retrospective studies must be comprised of a consecutive series of patients or randomly selected patients to minimize the threat of bias. (https://www.ecri.org/Products/Pages/htais.aspx)"			

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	"Option 3: AHRQ In 2002, The U.S. Department of Health and Human Services AHRQ collaborated with experts from the private and public sector to identify evidence classification methods and systems and provided recommendations. As a part of this report, the authors identified 19 generic systems to assess study quality that fully addressed all key quality domains. Only three of these systems were used for both RCTs and observational studies. While RCTS have the ability to minimize important potential bias, some experts prefer using studies with larger aggregate samples or studies with more diverse populations or different practice settings, which are typical of observational studies. Therefore, AHRQ recognizes the value of both categories of study design and offers key quality domains for systematic reviews, randomized controlled trials, observational studies, and diagnostic test studies." (http://www.ahrq.gov/clinic/epcsums/strengthsum.htm) "Option 4: SORT The editors of the US family medicine and primary care journals (i.e., *American Family Physician, Family Medicine, Journal of Family Practice, Journal of the American Board of Family Practice,* and *BMJ-USA*) and the Family Practice Inquiries Network (FPIN) collaborated to develop a unified taxonomy for the strength of recommendations based on a body of evidence called SORT. This taxonomy recognizes and is in keeping with the recommendations of the AHRQ report mentioned above. Their instrument to rate the quality of a study takes systematic reviews, RCTs, case-control studies, cohort studies, consensus guidelines, bench research, and opinion into account. (Ebell MH, et al. J Am Board Fam Pract 2004;17:59–			

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	67.)" Commenter states that from the text above one can see that the ACOEM ranking system is markedly different than other, more widely respected and accepted scales as delineated above. Commenter states that they have attached a side by-side comparison of these various scales [contained in the rulemaking file] which makes the significant differences even more compelling. Commenter indicates that experimental studies (RCTs) and observational studies (non-randomized) should be considered complimentary. Commenter states that the former offers internal validity, the latter external validity. Commenter states that the former tests a research hypothesis; the latter takes the hypothesis and injects it into a "real world" setting. Commenter states that observational studies allow for longer-term follow-up of effectiveness, economic analysis of alternate treatments, and more. Commenter states that excluding this body of evidence prohibits an exhaustive, fair and balanced review of treatment options, which is not in the best interest of patients. Commenter requests that California delete reference and use of ACOEM's evidence ranking system, and instead insert one of the alternatives options highlighted in his comments.			
9792.25(c)(1)(B)	Commenter references §9792.25 and questions whether this section is too stringent and limiting. Commenter also references language in §9792.25(c)(1)(B) in reference to Table B—Strength of Evidence Ratings, which states "Levels of evidence shall be used to rate the quality of the body of evidence. The body of evidence shall consist of all studies on a given topic that are used to develop evidence based recommendations. Levels of evidence	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Disagree.** See response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1) above. Moreover, DWC will consider commenter's suggestion that DWC adopt a different rating	See Action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers' Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), above.

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	shall be applied when studies are relevant to the topic and study working populations. Study outcomes shall be consistent and study data shall be homogeneous." Commenter states that this statement provides for no allowance for consensus of national organizations or community standards of practice.		methodology which will be considered in future MTUS updates.	
9792.26	Commenter thanks the members of the Medical Evidence Evaluation and Advisory Committee for their strong work over the past 1.5 years on the development of this Chronic Pain Chapter. Commenter states that their dedication and knowledge, combined with the DWC staff and leadership expertise, has resulted directionally in a very strong, fair and balanced approach both overall, as well as for the Chronic Pain Chapter.	Mark Tellez, Therapy Access Senior Manager Medtronic Neuromodulation Written and Oral Comment August 11, 2008	**Agree.**	None.
Appendix B- Chronic Pain Medical Treatment Guidelines EBRs	Commenter adds, however, that the DWC has appropriately done its own evidence searches and assessment for areas labeled as "under study" by ODG and for post-operative physical therapy. "Under study" is not an evidence grade. These searches and assessments appear to conform to the MTUS methodology.	Jeffrey S. Harris, M.D. August 11, 2008	**Agree. Agree** that the ODG chapter on pain uses the term "under study" for some individual treatment topics. The term "under study" indicates that the evidence was reviewed but ODG was unable to make a recommendation either in support or against the treatment based on the insufficiency of the evidence. Because the MTUS is presumed to be correct on the issue of extent and scope of medical treatment (Lab. Code, § 4604.5(a)), and because of the lack of guidance in the ODG chapter on pain on these topics, it is necessary for the DWC to conduct EBRs on these individual treatment topics to determine whether or not the treatment should be recommended. Just because the evidence is not sufficient, this does not necessarily mean that the individual treatment	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			topic should not have a recommendation.	
Appendix B- Chronic Pain Medical Treatment Guidelines EBRs ***Clonidine, Intrathecal***	Commenter notes the individual medical treatment guideline for Clonidine, Intrathecal. Specifically commenter references the sentence in the individual medical treatment which states "There is no evidence that intrathecal clonidine alone is effective in the treatment of pain after spinal cord surgery. Commenter indicates that this should refer to "back surgery" or "spinovertebral surgery". Commenter states that spinal cord surgery implies surgery on the spinal cord (tumors, AVM). Commenter indicates that pain following spinal cord surgery invariably by definition is neuropathic pain and hence Clonidine would be effective.	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Agree in part.** Commenter expresses concerns on the wording in Clonidine Intrathecal for spinal cord surgery. **Agree** that spinal cord surgery refers to tumors and AVM's, and that back surgery or spinovertebral surgery is more appropriate. However, ODG has revised their guidelines in the October 23, 2008 version, which DWC has adapted, and ODG has used different language and the guideline no longer includes "spinal cord" language. Therefore, commenter's concerns no longer apply to the current version as adapted. For the benefit of the public the revised individual topic guideline for ***Clonidine, Intrathecal*** is set forth in the Action portion of this chart.	The individual treatment guideline for ***Clonidine, Intrathecal*** of the Chronic Pain Guidelines is amended as follows based on the revised ODG version dated October 23, 2008: **"Clonidine, Intrathecal ~~[DWC]~~** ~~Recommended. The evidence supports the use of intrathecal clonidine alone or in conjunction with opioids (e.g., morphine) and local anesthetics (e.g., bupivicaine) in the treatment of Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy (CRPS/RSD). Intrathecal clonidine can also be used in conjunction with opioids for neuropathic pain. There is no evidence that intrathecal clonidine alone is effective in the treatment of pain after spinal cord surgery. There are no studies that address the use of intrathecal clonidine beyond 18 months.~~ Recommended only after a short-term trial indicates pain relief in patients

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				refractory to opioid monotherapy or opioids with local anesthetic. There is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. Clonidine is thought to act synergistically with opioids. Most studies on the use of this drug intrathecally for chronic non-malignant pain are limited to case reports. (Ackerman, 2003) Clonidine (Catapres) is a direct-acting adrenergic agonist prescribed historically as an antihypertensive agent, but it has found new uses, including treatment of some types of neuropathic pain.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Additional studies: One intermediate quality randomized controlled trial found that intrathecal clonidine alone worked no better than placebo. It also found that clonidine with morphine worked better than placebo or morphine or clonidine alone. (Ackermann, 2003) (Hassenbusch2, 2002) (Martin, 2001) (Raphael, 2002) (Roberts, 2001) (Siddall, 2000) (Taricco, 2006)"
Appendix B- Chronic Pain Medical Treatment Guidelines EBRs ***Topical Analgesics-Compounded***	Commenter references the individual medical treatment guideline for ***Topical Analgesics-Compounded***. Commenter states that this section needs clarification since it seems to confuse topical agents with transdermal agents. Commenter states that topical analgesics such as lidocaine have a local effect (lidocaine on an open wound is an extremely effective analgesic). Commenter adds that transdermal drugs (such as a Fentanyl Patch) are applied to the skin but have a systemic effect.	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Disagree.** DWC **disagrees** with the comment. Topical Analgesics – Compounded [DWC] was drafted as a companion guideline to the ODG Topical Analgesics guideline. ODG describes in detail the specific agents that fall under this category. Transdermal drugs such as fentanyl patch have separate and distinct guidelines. ODG has since absorbed the DWC Guidelines, and added additional language that specifies which agents fall under this topic heading. Although it is understood that it is useful to distinguish transdermal drugs versus topical analgesics, this educational distinction is not necessary as the adapted revised ODG October 23, 2008 guidelines distinguish individual guidelines transdermal	The individual treatment guideline for ***Topical Analgesics-Compounded*** of the Chronic Pain Guidelines is amended as follows based on the revised ODG version dated October 23, 2008: **"Topical Analgesics, – ~~C~~compounded ~~[DWC]~~** Not recommended. There is ~~no~~ mixed evidence ~~that~~ about whether compounding topical medications, such as adding an anti-inflammatory agent to capsaicin, is more efficacious than the single medication. Furthermore, ~~the~~ a recent FDA ~~has issued warnings~~ warning ~~on~~ about the potential dangers of

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			agents from topical agents. For the benefit of the public the revised individual topic guideline for ***Topical Analgesics-Compounded*** is set forth in the Action portion of this chart.	compounding topical medication containing local anesthetics supersedes any recommendation (U.S. Food and Drug Administration, FDA News, December 5, 2006, FDA Warns Five Firms to Stop Compounding Topical Anesthetic Creams. (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01516.html) The FDA warns that ~~E~~exposure to high concentrations of local anesthetics, like those in compounded topical anesthetic creams, can cause grave reactions (including seizures, ~~and~~ irregular heartbeats and death). ~~At least two deaths have been connected to compounded topical anesthetic creams. (FDA Advisory 12/05/06)~~ Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				growth factor). (Argoff, 2006) There is little to no research to support the use of many [of] these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments ***Clonidine, Intrathecal [DWC]***	Commenter states that the recommendations for CRPS intrathecal clonidine are potentially misapplied from evidence from spinal cord patients. Commenter indicates that while possibly appropriate in some patients, the proposed guidelines give the impression of standard of care, when clearly it should be more conservative: "*generally not recommended, … although … may be indicated in patients who have failed multiple trials of different oral medications and have undergone independent psychological consultation including psychometric testing that does not reveal a contraindication.*" (DWC page 38, page 25 par 1.)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Agree in part.** Commenter expresses concerns with the wording in Clonidine, Intrathecal [DWC] guideline. Commenter states that the guideline appears to give the impression that the treatment is the standard of care, when the guideline should be more conservative. Agree that the Clonidine, Intrathecal guideline should be clarified to qualify the treatment as an alternative treatment after failure of less invasive approaches. Following an evidence-based review, ODG has updated the guideline in the October 23, 2008 version, which DWC has adapted. The updated ODG guideline now provides, in relevant part, that the treatment is "Recommended only after a short-term trial indicates pain relief in patients refractory to opioid monotherapy or opioids with local anesthetic."	See action taken in connection with comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated August 11, 2008 on Appendix B-Chronic Pain Medical Treatment Guidelines EBRs, ***Clonidine, Intrathecal***, above.
9792.24.2(a) Chronic Pain Medical Treatment	Commenter states that the draft of the proposed chronic pain medical treatment guidelines suggests that SSRIs are efficacious, that the evidence is	ACOEM Barry Eisenberg, Executive Director	**Disagree.** Commenter is incorrect in stating that "SSRI antidepressants are uniformly	Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, **Part**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines **Part 2.** Pain Intervention and Treatments ***Antidepressants for neuropathic pain***	strongest for use of anti-depressants for neuropathic pain, much less evidence for non-neuropathic pain and that disorders generally respond equally to these agents. Commenter indicates that to the contrary, there is robust evidence from numerous moderate and high quality studies that SSRI antidepressants are uniformly ineffective for treatment of chronic painful conditions with the sole exception of fibromyalgia. (Dickens 00, Atkinson 99, Atkinson 07). DWC page 11, par 60.)	August 7, 2008	ineffective for treatment of chronic painful conditions with the sole exception of fibromyalgia." The DWC guidelines provide that SSRIs should be used only as option after tricyclic antidepressants fail. Moreover, DWC disagrees with the comment that the guideline provides "disorders generally respond equally to these agents." The guideline provides that it is "[r]ecommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain." Nevertheless and to clarify the guideline, ODG conducted its own evidence-based review, and has reorganized, re-named and updated the Antidepressants for neuropathic pain (now under the heading Antidepressant for chronic pain) guidelines in the October 23, 2008 version. DWC proposes to adapt the guideline into its chronic pain medical treatment guidelines.	**2.** Pain Intervention and Treatments, ***Antidepressants for neuropathic pain*** has been amended as follows: "**Antidepressants for chronic pain** "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain~~,~~. ~~with duration of about 4-6 weeks required to effectively measure treatment outcome. Have caution regarding sedation with the tricyclics and some other medications due to increased risk of accidents.~~ (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, ~~and at a lower dose than the antidepressant effect~~ whereas antidepressant effect takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				quality and duration, and psychological assessment. ~~(See also Comorbid psychiatric disorders.)~~ Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. (Additional side effects are listed below for each specific drug.) It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. (Perrot, 2006) (Schnitzer, 2004) (Lin-JAMA, 2003) (Salerno, 2002) (Moulin, 2001) (Fishbain, 2000) (Taylor, 2004) (Gijsman, 2004) (Jick-JAMA, 2004) (Barbui, 2004) (Asnis, 2004) (Stein, 2003) (Pollack, 2003) (Ticknor, 2004) (Staiger, 2003) ~~For more detailed recommendations, see Antidepressants for~~

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				~~neuropathic pain and Antidepressants for non-neuropathic pain.~~ Long-term effectiveness of anti-depressants has not been established. (Wong, 2007) The effect of this class of medication in combination with other classes of drugs has not been well researched. (Finnerup, 2005) The "number needed to treat" (NNT) methodology (calculated as the reciprocal value of the response rate on active and placebo) has been used to calculate efficacy of the different classes of antidepressants. (Sindrup, 2005) ~~Also see Comorbid psychiatric disorders.~~ ***"Specifically studied underlying pain etiologies:*** (also see below for specific drugs) *Neuropathic pain:* Recommended (tricyclic antidepressants) as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. (Saarto-Cochrane, 2007) (ICSI, 2007) Other recent reviews recommended both tricyclic antidepressants and SNRIs (i.e. duloxetine and venlafaxine) as first line

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				options. (Dworkin, 2007) (Finnerup, 2007) *Non-neuropathic pain:* Recommended as an option in depressed patients, but effectiveness is limited. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. In guidelines for painful rheumatic conditions recommended by Perrot, it was suggested that antidepressants may be prescribed as analgesics in non-depressed patients, with the first-line choice being tricyclics initiated at a low dose, increasing to a maximally tolerated dose. (Perrot, 2006) ***"Specific studied disease states*** *Fibromyalgia:* There have been 25 controlled trials that have studied the use of antidepressants for fibromyalgia, including 3 meta-analyses. Except for good results found with duloxetine and fibromyalgia (Arnold, 2007), the results generally show limited effectiveness on only a minority of patients for this condition, and most of these studies evaluated tricyclics.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				(Perrot, 2006) (Moulin, 2001) A review of two double blind, placebo controlled trials concluded that duloxetine was safe and effective in women with fibromyalgia for up to 12 weeks (with long-term studies needed). (Arnold, 2007) There appears to be a large placebo effect of this class of medications in treatment of this condition. (Saarto-Cochrane, 2007) Another review indicated that there is strong evidence that amitriptyline is effective for fibromyalgia; more information is needed regarding the role of SNRIs and SSRIs, so tricyclics may also be used for the treatment of fibromyalgia. (Goldenberg, 2007) *Low Back Pain: Chronic:* A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. SSRIs have not been shown to be effective for low back pain (there was not a

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition. (Chou, 2007) Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. SSRIs do not appear to be beneficial. (Perrot, 2006) *Radiculopathy:* Antidepressants are an option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. (Dworkin, 2007) *Osteoarthritis:* No studies have specifically studied the use of antidepressants to treat pain from osteoarthritis. (Perrot, 2006) In depressed patients with osteoarthritis, improving depression symptoms was found to decrease pain and improve functional status. (Lin-JAMA, 2003) **"SPECIFIC**

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				ANTIDEPRESSANTS: ***Tricyclic antidepressants*** are recommended over selective serotonin reuptake inhibitors (SSRIs), unless adverse reactions are a problem. Caution is required because tricyclics have a low threshold for toxicity, and tricyclic antidepressant overdose is a significant cause of fatal drug poisoning due to their cardiovascular and neurological effects. Tricyclic antidepressants have been shown in both a meta-analysis (McQuay, 1996) and a systematic review (Collins, 2000) to be effective, and are considered a first-line treatment for neuropathic pain. (Namaka, 2004) (Dworkin, 2003) (Gilron, 2006) (Wolfe, 2004) (Dworkin, 2007) (Saarto-Cochrane, 2007) This class of medications works in both patients with normal mood and patients with depressed mood when used in treatment for neuropathic pain. (Sindrup, 2005) Indications in controlled trials have shown effectiveness in treating central post-stroke pain, post-herpetic neuralgia (Argoff, 2004), painful

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				diabetic and non-diabetic polyneuropathy, and post-mastectomy pain. Negative results were found for spinal cord pain and phantom-limb pain, but this may have been due to study design. (Finnerup, 2005) Tricyclics have not demonstrated significance in randomized-control trials in treating HIV neuropathy, spinal cord injury, cisplatinum neuropathy, neuropathic cancer pain, phantom limb pain or chronic lumbar root pain. (Dworkin, 2007) One review reported the NNT for at least moderate neuropathic pain relief with tricyclics is 3.6 (3-4.5), with the NNT for amitriptyline being 3.1 (2.5-4.2). The NNT for venlafaxine, calculated using 3 studies, was reported to be 3.1 (2.2-5.1). (Saarto-*Cochrane*, 2007) Another review reported that the NNT for 50% improvement in neuropathic pain was 2 to 3 for tricyclic antidepressants, 4 for venlafaxine, and 7 for SSRIs (Perrot, 2008). *Side-effect profile:* Tricyclics are contraindicated in patients with cardiac conduction disturbances

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				and/or decompensation (they can produce heart block and arrhythmias) as well as for those patients with epilepsy. For patients > 40 years old, a screening ECG is recommended prior to initiation of therapy. (Dworkin, 2007) (ICSI, 2007) They can create anticholinergic side effects of dry mouth, sweating, dizziness, orthostatic hypotension, fatigue, constipation, and urinary retention. (Finnerup, 2005) To minimize side effects, it is suggested that titration should be slow and based on the patient's response. (Namaka, 2004) An alternative choice may be a SNRI. (Finnerup, 2005) (Sindrup, 2005) (Dworkin, 2007) *Dosing Information:* *Amitriptyline*: *Neuropathic pain*: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007). *Fibromyalgia*: One review recommended the following dosing regimen: Start with

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				low doses, such as 5-10 mg 1-3 hours before bedtime. Dose may be increased by 5 mg at two-week intervals; final dose is dependent upon efficacy and patient tolerability to side effects. Doses that have been studied range from 25 to 50 mg at bedtime. (Goldenberg, 2007) ***"Selective serotonin and norepinephrine reuptake inhibitors (SNRIs):*** *Duloxetine (Cymbalta®)*: FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. *Side effects:* CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs.2% for placebo), insomnia (8-13% vs. 6-7% for

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				placebo). GI: nausea and vomiting (5-30%), weight loss (2%). Duloxetine can worsen diabetic control in some patients. It also causes sexual dysfunction. (Maizels, 2005) *Dosing:* 60 mg once a day as an off-label option for chronic pain syndromes. Dosage adjustment may be required in patients with renal insufficiency. *Venlafaxine (Effexor®):* FDA-approved for anxiety, depression, panic disorder and social phobias. Off-label use for fibromyalgia, neuropathic pain, and diabetic neuropathy. *Side-effect profile:* CNS: (> 5%) drowsiness, weakness, dizziness, dry mouth, insomnia, nervousness/anxiety (13/6% vs. 6/3%), tremor, headache, seizures. GI: N&V, constipation, weight loss (2-18%). Pre-existing hypertension should be controlled. Cholesterol may be increased (5%). Sexual dysfunction has also been noted. (Maizels, 2005) (ICSI, 2007) *Dosing: Neuropathic pain (off-label indication):* 37.5 mg once daily, increase by

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				37.5 mg per week up to 300 mg daily. (Maizels, 2005) (ICSI, 2007) *Trial period:* Some relief may occur in first two weeks; full benefit may not occur until six weeks. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation. ***"Bupropion (Wellbutrin®),*** a second-generation non-tricyclic antidepressant (a noradrenaline and dopamine reuptake inhibitor) has been shown to be effective in relieving neuropathic pain of different etiologies in a small trial (41 patients). (Finnerup, 2005) While bupropion has shown some efficacy in neuropathic pain there is no evidence of efficacy in patients with non-neuropathic chronic low back pain. (Katz, 2005) Furthermore, a recent review suggested that bupropion is generally a third-line medication for diabetic neuropathy and may be considered when patients have not had a response to a tricyclic or SNRI. (Dworkin, 2007)

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Side-effect profile: Headache, agitation, insomnia, anorexia, weight loss *Dosing Information: Neuropathic pain (off-label indication):* 100 mg once daily, increase by 100 mg per week up to 200 mg twice daily. (Maizels, 2005) ***"Selective serotonin reuptake inhibitors (SSRIs)***, a class of antidepressants that inhibit serotonin reuptake without action on noradrenaline, are controversial based on controlled trials. (Finnerup, 2005) (Saarto-*Cochrane*, 2005) It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain. (Namaka, 2004) More information is needed regarding the role of SSRIs and pain."
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part 2.** Pain Intervention and Treatments ***Biofeedback***	Commenter states that the draft of the chronic pain medical treatment guidelines uses, in part, references which are not high or moderate quality studies. It uses proprietary sponsored guidelines which are potentially not relevant to the working population. It is confusing, equivocating biofeedback with psychotherapy, seemingly randomly. (DWC page 20.)	ACOEM Barry Eisenberg, Executive Director August 7, 2008	**Disagree.** The guideline specifically states that biofeedback may be performed only in conjuction with cognitive behavioral therapy. The guideline is based on a thorough review of the available evidence, and 21 citations are listed which represents a large review of the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			available evidence.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines **Part I: Introduction Pain Outcomes and Endpoints**	Commenter requests that the following language be inserted in the **Pain Outcomes and Endpoints s**ection of the Indroduction: "The foregoing consideration not withstanding, the control of pain, the reduction of suffering, the development of self-maintenance skills, the improvement of mental state, and the improvement of family relationships, are equally important considerations in the management of persistent pain."	Philipp M. Lippe, M.D. Medical Corporation, Consultant August 11, 2008	**Agree in part.** DWC agrees with the concept as set forth by commenter that controling pain as it relates to quality of life is an important consideration. DWC determined that clarifying the language in this paragraph is necessary to address the purpose of the treatment plan for a chronic condition to maintain the patient's level of function. Language from the California Medical Board was used to define the treatment plan for chronic pain and the need for periodic review, and the revised sentence addresses commenter's concern. The second paragraph is modified by inserting the following new language, thus: "The physician should periodically review the course of treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of pain management depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. When prescribing controlled substances for pain, satisfactory response to	The second paragraph of the section subtitled: Pain Outcomes and Endpoints, at page 9 of the Introduction of the Chronic Pain Medical Treatment Guidelines is amended to add the following sentence at the end of the paragraph as follows: "When prescribing controlled substances for pain, satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. (http://www.medbd.ca.gov/pain_guidelines.html).

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. (http://www.medbd.ca.gov/pain_guidelines.html)."	
9792.24.2 General/ Compliance with the Statutes-Lab. Code, §§ 4604.5(b), 5307.27	Commenter indicates that the statute further provides the MTUS at a minimum shall address the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers compensation cases. Commenter indicates that for many of the treatment procedures and modalities in the chronic pain section, this minimum is not met.	Keith Bateman, Vice President, Property Casualty Insurers Association of America, August 12, 2008	**Disagree.** Labor Code section 5307.27 requires that the MTUS "address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases." Labor Code section 4604.5(b) provides, in relevant part that, "the guidelines [adopted into the MTUS] shall be designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and shall constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions." Labor Code section 4600(b) provides that the injured worker is entitled to medical treatment that is consistent with the MTUS. A treating physician's request for authorization for medical treatment is subjected to utilization review by the workers' compensation claims administrator pursuant to Labor Code section 4610. Under the utilization review statute and	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			regulations (Lab. Code § 4610, 8 CCR 9792. 6 et. al.) the claims administrator may approve a request for authorization, but only a physician makes a determination to modify, delay or deny the request for authorization. This involves a physician who interprets the request based on the MTUS, and then a physician-to-physician discussion regarding the medical request for authorization. The proposed regulations define "chronic pain" as "any pain that persists beyond the anticipated time of healing." The chronic pain medical treatment guidelines are composed of two parts: Part 1: Introduction, and Part 2: Pain Interventions and Treatments. The two sections are interdependent. The Introduction provides that "[i]f the patient continues to have pain that persists beyond the anticipated time of healing, without plans for curative treatment, such as surgical options, the chronic pain medical treatment guidelines apply" (Introduction, at p. 1). The Introduction further provides that "[a]s is the case with all chronic medical conditions, chronic pain must be managed, not cured" (Introduction, at p. 5). **Because chronic pain is pain that persists beyond the anticipated time of healing, it is indeterminate in its**	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			duration. Thus the "duration" requirement as set forth in Labor Code section 5307.27 cannot always be specifically determined when addressing chronic pain. When addressed in some treatments, however, such as acute exarcerbations in a patient with chronic pain, the duration may be defined as short term. Further, there are some drugs that are to be used on a short term basis only because of adverse effects (see, Benzodiazepines is recommended for a short term use because risk of dependency. Guidelines, at p. 23.) With regard to the frequency and intensity requirements of the statute, the MTUS regulations and the chronic pain medical treatment guidelines within it harmonize the requirements of Labor Code section 5307.27 and Labor Code section 4604.5(b), which state that the guidelines are intended to provide "an analytical framework for the evaluation and treatment of injured workers." In treating the injured worker under the chronic pain medical treatment guidelines, the treating physician is required to exercise clinical judgment by "tailor[ing) medications and dosages to the individual taking into consideration patient-specific variables such as comorbidities, other medications, and allergies.	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			The physician should be knowledgeable regarding prescribing information and adjust the dosing to the individual patient" (Introduction at p. 7). This language addresses the concern regarding frequency and intensity because clinical judgment is necessary to determine frequency and intensity in many instances. In that regard, the Introduction provides that "[s]election of treatment must be tailored for the individual case" (Introduction at p. 8).	