§ 9792.20. Medical Treatment Utilization Schedule - Definitions

As used in this Article:

(a) “ACOEM” means the American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines published by the Reed Group containing evidenced-based medical treatment guidelines for conditions commonly associated with the workplace. ACOEM guidelines may be obtained from the Reed Group (http://go.reedgroup.com/mtus).

(b) “Chronic pain” means pain lasting three or more months from the initial onset of pain.

(c) “Claims administrator” is a self-administered workers' compensation insurer, a self-administered self-insured employer, a self-administered legally uninsured employer, a self-administered joint powers authority, a third-party claims administrator, or the California Insurance Guarantee Association.

(d) “Evidence-Based Medicine (EBM)” means a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient values.

(e) “Functional improvement” means 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 of the medical evaluation and treatment; and a reduction in the dependency on continued medical treatment.

(f) “Medical treatment” is care which is reasonably required to cure or relieve the employee from the effects of the industrial injury consistent with the requirements of sections 9792.20–9792.26.

(g) “Medical treatment guidelines” means the most current version of written recommendations 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 reviewed and updated within the last five years.

(h) “Nationally recognized” means published in a peer-reviewed medical journal; or developed, endorsed and disseminated by a national organization with affiliates based in two or more U.S. states and is the most current version.
(i) “ODG” means the Official Disability Guidelines published by the Work Loss Data Institute containing evidenced-based medical treatment guidelines for conditions commonly associated with the workplace. ODG guidelines may be obtained from the Work Loss Data Institute, 169 Saxony, #101, Encinitas, California 92024 (www.ODG@worklossdata.com).

(j) “Peer reviewed” means that a study’s content, methodology and results have been evaluated and approved prior to publication by an editorial board of qualified experts.

(k) “Scientifically based” means based on scientific literature, wherein the body of literature is identified through performance of a literature search, the identified literature is evaluated, and then used as the basis to support a recommendation.

(l) “Strength of Evidence” establishes the relative weight that shall be given to scientifically based evidence.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

§ 9792.21. Medical Treatment Utilization Schedule

(a) The Administrative Director adopts the Medical Treatment Utilization Schedule (MTUS) consisting of section 9792.20 through section 9792.26.

(b) The MTUS is based on the principals of Evidenced-Based Medicine (EBM). EBM is a systematic approach to making clinical decisions which allows the integration of the best available evidence with clinical expertise and patient values. EBM is a method of improving the quality of care by encouraging practices that work and discouraging those that are ineffective or harmful. EBM asserts that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for making clinical decisions. Instead, EBM requires the evaluation of medical evidence by applying an explicit systematic methodology to determine the quality and strength of evidence used to support the recommendations for a medical condition or injury. The best available evidence is then used to guide clinical decision making.

(c) The recommended guidelines set forth in the MTUS are presumptively correct on the issue of extent and scope of medical treatment. The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment of work-related illness or injury to achieve functional improvement, return-to-work, and disability prevention. The MTUS shall be the primary source of guidance for treating physicians and physician reviewers for the evaluation and treatment of injured workers.
(d) Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. There are two limited situations that may warrant treatment based on recommendations found outside of the MTUS.

(1) First, if a medical condition or injury is not addressed by the MTUS, medical care shall be in accordance with other medical treatment guidelines or peer-reviewed studies found by applying the Medical Evidence Search Sequence set forth in section 9792.21.1.

(2) Second, if the MTUS’ presumption of correctness is successfully challenged. The recommended guidelines set forth in the MTUS are presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by a preponderance of scientific medical evidence establishing that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. The presumption created is one affecting the burden of proof. Therefore, the treating physician who seeks treatment outside of the MTUS bears the burden of rebutting the MTUS’ presumption of correctness by a preponderance of scientific medical evidence.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5, 4610.5 and 5307.27, Labor Code.

§ 9792.21.1. Medical Evidence Search Sequence

(a) Treating physicians and medical reviewers shall conduct the following medical evidence search sequence for the evaluation and treatment of injured workers.

(1) Search the recommended guidelines set forth in the current MTUS to find a recommendation applicable to the injured worker’s medical condition or injury.

(2) In the limited situation where a medical condition or injury is not addressed by the MTUS or if the MTUS’ presumption of correctness is being challenged, then:

(A) Search the most current version of ACOEM or ODG to find a recommendation applicable to the injured worker’s medical condition or injury. Choose the recommendation that is supported with the best available evidence according to the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1. If no applicable recommendation is found, or if the treating physician or reviewing physician believes there is another recommendation supported by a higher quality and strength of evidence, then

(B) Search the most current version of other evidence-based medical treatment guidelines that are recognized by the national medical community and are scientifically based to find a recommendation applicable to the injured worker’s medical condition or injury. Choose the recommendation that is supported with the best available evidence according to the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1. Medical treatment guidelines can be found in the National Guideline

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations
Clearinghouse that is accessible at the following website address: www.guideline.gov/. If no applicable recommendation is found, or if the treating physician or reviewing physician believes there is another recommendation supported by a higher quality and strength of evidence, then

(C) Search for current studies that are scientifically-based, peer-reviewed, and published in journals that are nationally recognized by the medical community to find a recommendation applicable to the injured worker’s medical condition or injury. Choose the recommendation that is supported with the best available evidence according to the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1. A search for peer-reviewed published studies may be conducted by accessing the U.S. National Library of Medicine’s database of biomedical citations and abstracts that is searchable at the following website: www.ncbi.nlm.nih.gov/pubmed. Other searchable databases may also be used.

(b) After conducting the medical evidence search in the sequence specified above:

(1) Treating Physicians

(A) If the medical condition or injury is not addressed by the MTUS, then the treating physician may provide in the Request for Authorization (RFA) or in an attachment to the RFA a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.

1. The citation provided by the treating physician shall be the primary source relied upon which he or she believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.

2. If the treating physician provides more than one citation, then a narrative shall be included by the treating physician in the RFA or in an attachment to the RFA explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury but is not addressed by the primary source cited.

(B) If the medical condition or injury is addressed by the MTUS but the treating physician is attempting to rebut the MTUS’ presumption of correctness, then the treating physician shall provide in the RFA or in an attachment to the RFA the following: a clear and concise statement that the MTUS’ presumption of correctness is being challenged; a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury; and a copy of the entire study or the relevant sections of the guideline containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.
1. The citation and copy of the study or copy of the relevant sections of the guideline provided by the treating physician shall be the primary source relied upon which he or she believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.

2. If the treating physician provides more than one citation, then a copy of the additional study(ies) or copy of the additional relevant sections of the guideline(s) along with a narrative shall be included by the treating physician in the RFA or in an attachment to the RFA explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury but is not addressed by the primary source cited.

(2) Utilization Review Physicians

(A) If the RFA is being modified, delayed or denied, then the Utilization Review physician shall provide in the Utilization Review decision, in addition to the requirements set forth in section 9792.9.1(e), a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.

1. The citation provided by the Utilization Review physician shall be the primary source relied upon which he or she believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.

2. If the Utilization Review physician provides more than one citation, then a narrative shall be included by the reviewing physician in the Utilization Review decision explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury but is not addressed by the primary source cited.

(3) Independent Medical Review Physicians

(A) If the Utilization Review Decision delays, denies or modifies an injured worker’s request for treatment and review of that decision is requested through Independent Medical Review, then the Independent Medical Review physician shall provide in the Independent Medical Review decision, in addition to the requirements set forth in section 9792.10.6(d), a citation to the guideline or study containing the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.
1. The citation provided by the Independent Medical Review physician shall be the primary source he or she relied upon which contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury.

2. If the Independent Medical Review physician provides more than one citation, then a narrative shall be included by the reviewing physician in the Independent Medical Review decision explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury but is not addressed by the primary source cited.

(c) If the treating physician and/or the Utilization Review physician and/or the Independent Medical Review physician cited different guidelines or studies containing recommendations that are at variance with one another, the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1 shall be applied by the reviewing physician to determine which one of the recommendations is supported by the best available evidence.

(d) The format of the citations provided by the treating physician, Utilization Review physician, and Independent Medical physician, shall include the following

(1) When citing the MTUS:

(A) Indicate the MTUS is being cited and the effective year of the guideline;

(B) Title of chapter (e.g., Low Back Complaints); and

(C) Section of chapter (e.g., Surgical Considerations).

(2) When citing other medical treatment guidelines:

(A) Title of organization publishing the guideline (e.g., ACOEM or ODG);

(B) Year of publication;

(C) Title of chapter; and

(D) Section of chapter.

(3) When citing a peer-reviewed study:

(A) First author’s last name and first name initial;

(B) Published article title;

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations
Employers and their representatives, at their discretion, may approve medical treatment beyond what is covered in the MTUS or supported by the best available medical evidence in order to account for medical circumstances warranting an exception. The treating physician should provide clear documentation of the clinical rationale focusing on expected objective functional gains afforded by the requested treatment and impact upon prognosis.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5, 4610.5 and 5307.27, Labor Code.

§ 9792.22. General Approaches.

(a) The Administrative Director adopts and incorporates by reference into the MTUS specific guidelines set forth below from the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines (ACOEM Practice Guidelines) for the following chapters.


(3) Initial Approaches to Treatment (ACOEM June 30, 2017).


Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5, 4610.5 and 5307.27, Labor Code.

§ 9792.23. Clinical Topics

(a) The Administrative Director adopts and incorporates by reference a series of medical treatment guidelines into the MTUS commencing with section 9792.23.1.

(b) For all conditions or injuries not addressed in the MTUS treatment guidelines, the authorized treatment and diagnostic services shall be in accordance with other
scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community pursuant to section 9792.21(d)(1).

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.


The Administrative Director adopts and incorporates by reference the Cervical and Thoracic Spine Disorders Guideline (ACOEM May 27, 2016) into the MTUS from the ACOEM Practice Guidelines.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.23.2. Shoulder Disorders Guideline.

The Administrative Director adopts and incorporates by reference the Shoulder Disorders Guideline (ACOEM August 1, 2016) into the MTUS from the ACOEM Practice Guidelines.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.23.3. Elbow Disorders Guideline.

The Administrative Director adopts and incorporates by reference the Elbow Disorders Guideline (ACOEM 2013) into the MTUS from the ACOEM Practice Guidelines.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.


The Administrative Director adopts and incorporates by reference the Hand, Wrist, and Forearm Disorders Guideline (ACOEM June 30, 2016) into the MTUS from the ACOEM Practice Guidelines.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.23.5. Low Back Disorders Guideline.

The Administrative Director adopts and incorporates by reference the Low Back Disorders Guideline (ACOEM February 24, 2016) into the MTUS from the ACOEM Practice Guidelines.

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations

The Administrative Director adopts and incorporates by reference the Knee Disorders Guideline (ACOEM October 28, 2015) into the MTUS from the ACOEM Practice Guidelines.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.23.7. Ankle and Foot Disorders Guideline.

The Administrative Director adopts and incorporates by reference the Ankle and Foot Disorders Guideline (ACOEM September 2015) into the MTUS from the ACOEM Practice Guidelines.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.23.8. Stress Related Conditions.

The Administrative Director adopts and incorporates by reference the Chronic Pain Guideline (ACOEM May 2017) into the MTUS from the ACOEM Practice Guidelines for psychological treatment and evaluation related to chronic pain. If the injured worker’s psychological condition, treatment, or evaluation is unrelated to chronic pain, then medical care and evaluation shall be in accordance with other medical treatment guidelines or peer-reviewed studies found by applying the Medical Evidence Search Sequence set forth in section 9792.21.1.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.23.9. Eye Disorders Guideline.

The Administrative Director adopts and incorporates by reference the Eye Disorders Guideline (ACOEM April 1, 2017) into the MTUS from the ACOEM Practice Guidelines.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

The Administrative Director adopts and incorporates by reference the Hip and Groin Guideline (ACOEM May 1, 2011) into the MTUS from the ACOEM Practice Guidelines.

Note: Authority cited: Sections 133, 4603.5 and 5307.27, Labor Code. Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.23.11. Occupational/Work-Related Asthma Medical Treatment Guideline.

The Administrative Director adopts and incorporates by reference the Occupational/Work-Related Asthma Medical Treatment Guideline (ACOEM January 4, 2016) into the MTUS from the ACOEM Practice Guidelines.

Note: Authority cited: Sections 133, 4603.5 and 5307.27, Labor Code. Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.


The Administrative Director adopts and incorporates by reference the Occupational Interstitial Lung Disease Guideline (ACOEM January 4, 2016) into the MTUS from the ACOEM Practice Guidelines.

Note: Authority cited: Sections 133, 4603.5 and 5307.27, Labor Code. Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.24.1. Acupuncture Medical Treatment Guidelines

Guidance for acupuncture treatment and evaluation are contained in the applicable Clinical Topics guidelines, and/or Chronic Pain Guideline, and/or Opioid Guideline.

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code. Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.24.2. Chronic Pain Guideline.

The Administrative Director adopts and incorporates by reference the Chronic Pain Guideline (ACOEM May 15, 2017) into the MTUS from the ACOEM Practice Guidelines for the treatment and evaluation of patients who have chronic pain as defined in section 9792.20. This guideline addresses a general approach to patients with chronic pain and the psychological and behavioral aspects of chronic pain. This guideline also addresses a few specific chronic pain disorders (i.e., complex regional pain syndrome, fibromyalgia, neuropathic pain). Guidance for treatment and evaluation of chronic pain disorders not specifically addressed in this guideline are contained in the Clinical Topics guidelines and/or Opioid Guideline.
§ 9792.24.3. Postoperative Rehabilitation Guidelines.

Guidance for postoperative rehabilitation treatment and evaluation are contained in the Clinical Topics guidelines, and/or Chronic Pain Guideline and/or Opioid Guideline. The post-operative rehabilitation treatment recommendations apply to visits during the post-operative period only and to surgeries as defined in those guidelines. At the conclusion of the post-operative period, treatment reverts back to the applicable 24-visit limitation for chiropractic, occupational therapy, and physical therapy pursuant to Labor Code section 4604.5(c)(1).

Authority cited: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code. Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.24.4. Opioids Guideline.

(a) The Administrative Director adopts and incorporates by reference the Opioids Guideline (ACOEM April 20, 2017) into the MTUS from the ACOEM Practice Guidelines.

(b) The Opioids Guideline describes the appropriate use of opioid medications as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain. This guideline applies when the use of opioid medications is being considered as part of the treatment regimen.

Note: Authority cited: Sections 133, 4603.5 and 5307.27, Labor Code. Reference: Sections 77.5, 4600, 4604.5 and 5307.27, Labor Code.

§ 9792.25. Quality and Strength of Evidence – Definitions

(a) For purposes of sections 9792.25-9792.26, the following definitions shall apply:

(1) “Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument” means a tool designed primarily to help guideline developers and users assess the methodological rigor and transparency in which a guideline is developed. The Administrative Director adopts and incorporates by reference the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, May 2009 into the MTUS from the following website: www.agreetrust.org. A copy of the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, May 2009 version 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.
(2) “Bias” means any tendency to influence the results of a trial (or its interpretation) other than the experimental intervention. Biases include but are not limited to vested interests such as financial interests, academic interests, and industry influence; confounding variables, inadequate generation of the randomization sequence, inadequate concealment of allocation, selection, lack of blinding, selective outcome reporting, failure to do intention-to-treat analysis, early stopping, and publication.

(3) “Biologic plausibility” means the likelihood that existing biological, medical, and toxicological knowledge explains observed effect.

(4) “Blinding” means a technique used in research to eliminate bias by hiding the intervention from the patient, clinician, and any others who are interpreting results.

(5) “Case-control study” means a retrospective observational epidemiologic study of persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing the diseased and non-diseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups.

(6) “Case report” means a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient. Case reports usually describe an unusual or novel occurrence.

(7) “Case-series” means a group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients. This includes demographic information (for example, age, gender, ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment. This may be done prospectively or retrospectively.

(8) “Cohort study” (also known as “follow-up study” or “prospective study”) means an epidemiologic study in which two or more groups of people that are free of disease and that differ according to the extent of exposure to a potential cause of the disease are compared with respect to the incidence (occurrence of the disease) in each of the groups. This may include a comparison of treated and non-treated patients. The main feature of cohort study is observation of large numbers of people over a long period of time (commonly years) with comparison of incidence rates in groups that differ in exposure levels.

(9) “Concealment of allocation” means precautions taken to ensure that the groups to which patients or subjects are assigned as part of a study are not revealed prior to definitively allocating them to their respective groups.

(10) “Confounding variable” means extrinsic factor associated with the exposure under study and cause of the outcome.
(11) “Cross-sectional study” means a study that examines the relationship between diseases (or other health-related characteristics) and other variables of interest as they exist in a defined population at one particular time. Note that disease prevalence rather than disease incidence is normally recorded in a cross-sectional study. The temporal sequence of cause and effect cannot necessarily be determined in a cross-sectional study.

(12) “Diagnostic test” means any medical test performed to confirm, or determine the presence of disease in an individual suspected of having the disease, usually following the report of symptoms, or based on the results of other medical tests. Some examples of diagnostic tests include performing a chest x-ray to diagnose pneumonia, and taking skin biopsy to detect cancerous cells.

(13) “Disease incidence” means new cases of disease or condition over a period of time.

(14) “Disease prevalence” means rate of a disease or condition at any particular point in time.

(15) “Expert opinion” means a determination by experts, through a process of evidenced-based thinking, that a given practice should or should not be recommended, and the opinion is published in a peer-reviewed medical journal.

(16) “Inception cohort study” means a group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition, or before the condition develops.

(17) “Index test” means the diagnostic procedure or test that is being evaluated in a study.

(18) “Intention to treat” means a procedure in the conduct and analysis of randomized controlled trials. All patients allocated to a given arm of the treatment regimen are included in the analysis whether or not they received or completed the prescribed regimen. Failure to follow this step defeats the main purpose of random allocation and can invalidate the results.

(19) “Low risk of bias” means those trials or studies that contain methodological safeguards to protect against biases related to vested interests such as financial interests, academic interests, industry influence, or other biases related to the generation of the randomization sequence, concealment of allocation, selection, blinding, selective outcome reporting, early stopping, and intention to treat.

(20) “Meta-analysis” means a mathematical process whereby results from two or more studies are combined using a method that provides a weight to each study that reflects the statistical likelihood (variance) that its results are more likely to be closer to the truth.

(21) “Post-marketing surveillance” means a procedure implemented after a drug has been licensed for public use. The procedure is designed to provide information on the actual use of the drug for a given indication and on the occurrence of side effects, adverse
reactions, etc. This is a method for identifying adverse drug reactions, especially rare (<1% incidence) ones.

(22) “Prognosis” means the prospect of survival and recovery from a disease as anticipated from the usual course of that disease or indicated by special features of the case.

(23) “Randomized trial” means a clinical experiment in which subjects in a population are allocated by chance into groups, usually called study and control groups, to receive or not receive an experimental diagnostic, preventive, or therapeutic procedure, maneuver, or intervention. The results are assessed by comparison of rates of disease, death, recovery, or other appropriate outcome in the study and control groups.

(24) “Reference standard” means the gold standard to which an index test is being compared.

(25) “Risk of bias” means a term that refers to the advertent or inadvertent introduction of bias into trials because of methodological insufficiencies to protect against biases related to vested interests such as financial interests, academic interests, industry influence, or other biases related to the generation of the randomization sequence, concealment of allocation, selection, blinding, selective outcome reporting, early stopping, and intention to treat.

(26) “Selective outcome reporting” means the failure to report all of the outcomes that are assessed in a trial, including a post hoc change in the primary outcome.

(27) “Systematic review” means the application of strategies that limit bias in the assembly, critical appraisal, and synthesis of all relevant studies on a specific topic. Systematic reviews focus on peer-reviewed publications about a specific health problem and use rigorous, standardized methods for selecting and assessing articles. A systematic review differs from a meta-analysis in not including a quantitative summary of the results. However, a meta-analysis may be part of a systematic review.

(28) “Treatment benefits” means positive patient-relevant outcome associated with an intervention, quantifiable by epidemiological measures such as absolute risk reduction and number needed to treat.

(29) “Treatment harms” means an adverse patient-relevant outcome associated with an intervention, identifiable by epidemiological measures such as absolute increased risk of occurrence or number needed to harm if possible, but also identifiable by post-marketing surveillance.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code. Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.
§ 9792.25.1 MTUS Methodology for Evaluating Medical Evidence

(a) When competing recommendations are cited to guide medical care, Utilization Review and Independent Medical Review physicians shall apply the MTUS Methodology for Evaluating Medical Evidence to evaluate the quality and strength of evidence used to support the recommendations that are at variance with one another. The MTUS Methodology for Evaluating Medical Evidence provides a process to evaluate studies, not guidelines. Therefore, the reviewing physician shall evaluate the underlying study or studies used to support a recommendation found in a guideline. Medical care shall be in accordance with the recommendation supported by the best available evidence. The MTUS Methodology for Evaluating Medical Evidence shall be applied as follows:

(1) The reviewing physician shall determine if different guidelines or studies were cited to guide the injured worker’s medical care by the treating physician, the Utilization Review physician and/or the Independent Medical Review physician that contain recommendations that are at variance with one another.

(2) If different guidelines or studies were cited to guide the injured worker’s medical care containing recommendations that are at variance with one another, the reviewing physician shall evaluate the quality of evidence by determining if the studies used to support the recommendations are applicable to the injured worker and his or her medical condition or injury. Applicability refers to the extent to which the individual patients, subjects, settings, interventions, and outcome measures of studies used to support a recommendation are similar to the worker and his or her medical condition or injury. A recommendation supported by inapplicable studies should not be used as the source to support, deny, delay or modify an RFA. Reviewing physicians shall provide an explanation of their rationale in the Utilization Review or Independent Medical Review decision if they conclude a recommendation is supported by studies inapplicable to the worker and his or her medical condition or injury.

(A) The evaluation of medical evidence can end after this step if a citation to a guideline or a study contains a recommendation supported by inapplicable studies and the other citation contains a recommendation that is supported by studies applicable to the injured worker’s medical condition or injury.

(3) If the guidelines or studies cited contain recommendations supported by studies applicable to the worker and his or her medical condition or injury, then the reviewing physician shall continue to evaluate the quality of evidence by determining what factors, if any, bias may have had in the studies used to support the recommendations. Factors to consider include, but are not limited to, vested interests such as financial interests, academic interests, industry influence, and the methodological safeguards to protect against biases related to the generation of the randomization sequence, concealment of allocation, blinding, selective outcome reporting, early stopping, intention to treat, and confounding bias. A recommendation supported by studies determined to be of poor quality due to the presence of bias should not be used as the source to support, deny, delay or modify an RFA. Reviewing physicians shall provide an explanation of their
rationale in the Utilization Review or Independent Medical Review decision if they conclude a recommendation is supported by studies determined to be of poor quality due to the presence of bias.

(A) The evaluation of medical evidence can end after this step if a citation to a guideline or a study contains a recommendation supported by studies determined to be of poor quality due to the presence of bias and the other citation contains a recommendation that is supported by studies determined to be of good quality due to the absence of bias.

(4) If the guidelines or studies cited contain recommendations supported by studies applicable to the worker and his or her medical condition or injury and if the recommendations are supported by studies that are determined to be of good quality due to the absence of bias, then the reviewing physician shall determine the strength of evidence used to support the differing recommendations by applying the Hierarchy of Evidence for Different Clinical Questions set forth in 9792.25.1(b). To apply the Hierarchy of Evidence for Different Clinical Questions, the following steps shall be taken:

(A) Determine the design of the study used to support the recommendation. Study designs are categorized as one of the following categories:

1. Systematic Review of:
   (aa) Randomized Controlled Trials
   (bb) Prospective or Cohort Studies

2. Randomized Controlled Trials

3. Observational studies:
   (aa) Prospective study or Cohort Study
   (bb) Cross-sectional study
   (cc) Case-control study
   (dd) Case-series
   (ee) Uncontrolled or observational study
   (ff) Case report

4. Published expert opinion
(B) Determine which of the four clinical questions in the MTUS Hierarchy of Evidence for Different Clinical Questions as set forth in Section 9792.25.2(b) the study is answering and then apply the corresponding hierarchy(ies) of evidence. The sequence to be followed for each of the four clinical questions is as follows:

1. If the original study answers the question “How useful is Treatment X in treating patients with Disease Y?” then the hierarchy of evidence set forth under Treatment Benefits shall apply.

2. If the original study answers the question “How useful is Test X in diagnosing patients with Disease Y?” then the hierarchy of evidence set forth under Diagnostic Test shall apply.

3. If the original study answers the question “What will happen to a patient with Disease Y if nothing is done?” then the hierarchy of evidence set forth under Prognosis shall apply.

4. If the original study answers the question “What are the harms of intervention (treatment or diagnostic test) X in patients with Disease Y?” then the hierarchy of evidence set forth under Treatment Harms shall apply.

(C) In each Clinical Question category, the levels of evidence are listed from highest to lowest, as defined by the principles of Evidence-Based Medicine. Levels of evidence shall be applied in the order listed. Recommendation for or against medical treatment based on a lower level of evidence shall be permitted only if every higher ranked level of evidence is inapplicable to the employee's medical condition.

1. The level of evidence for each published study (e.g. 1a, 1b, 2, etc.) shall be documented and included with the citation in the Utilization Review or Independent Medical Review decisions.

2. When relying on lower levels of evidence, a written statement shall be provided that states higher levels of evidence are absent.

(b) MTUS Hierarchy of Evidence for Different Clinical Questions shall apply:

**MTUS Hierarchy of Evidence for Different Clinical Questions**

<table>
<thead>
<tr>
<th>Evidence Level</th>
<th>Treatment Benefits</th>
<th>Diagnostic Test</th>
<th>Prognosis</th>
<th>Treatment Harms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>How useful is Treatment X in treating patients with Disease Y?</td>
<td>How useful is Test X in diagnosing patients with Disease Y?</td>
<td>What will happen to a patient with Disease Y if nothing is done?</td>
<td>What are the harms of intervention (treatment or diagnostic test) X in patients with Disease Y?</td>
</tr>
<tr>
<td></td>
<td>Systematic review</td>
<td>Systematic review</td>
<td>Systematic</td>
<td>Systematic review of</td>
</tr>
</tbody>
</table>

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations
<table>
<thead>
<tr>
<th>1a</th>
<th>of randomized controlled trials with low risk of bias</th>
<th>of high-quality prospective studies (homogeneous sample of patients, consecutively enrolled, all undergoing the index test and reference standard) or systematic review of randomized controlled trials with low risk bias</th>
<th>review of inception cohort studies or of control arms of randomized controlled trials with low risk of bias</th>
<th>randomized controlled trials with low risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>1b</td>
<td>Randomized controlled trials with low risk of bias</td>
<td>High-quality prospective study or cohort study or randomized controlled trials with low risk of bias</td>
<td>Inception cohort study or control arm from one randomized controlled trial with low risk of bias</td>
<td>Randomized controlled trials with low risk of bias</td>
</tr>
<tr>
<td>1c</td>
<td>One or more randomized controlled trials with identified risks of bias (or systematic review of such trials)</td>
<td>Biased cross-sectional study</td>
<td>Cohort study or control arm of randomized controlled trials with identified risks of bias</td>
<td>Prospective study</td>
</tr>
<tr>
<td>2</td>
<td>Non-randomized cohort studies that include controls</td>
<td>Case-control study enrolling a broad spectrum of patients and controls with conditions that may be confused with the disease being considered</td>
<td>Case-series or case control studies</td>
<td>Randomized controlled trial(s) with identified risk of bias</td>
</tr>
<tr>
<td>3</td>
<td>Case-control studies or historically controlled studies</td>
<td>Case-control study using severe cases and healthy controls</td>
<td>Non-randomized controlled cohort/follow-up study (post-marketing surveillance)</td>
<td>Consistent case reports</td>
</tr>
</tbody>
</table>

Uncontrolled studies | Uncontrolled | Consistent case reports |
(case studies or case reports) (for example, individual case safety reports from US Food and Drug Administration, which are available at the following website: www.fda.gov/ForIndustry/DataStandards/IndividualCaseSafetyReports/default.htm

Published expert opinion

Published expert opinion

Published expert opinion

Toxicological or mechanistic data that demonstrate or support biologic plausibility

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, 4610.5 and 5307.27, Labor Code.

§ 9792.26. Medical Evidence Evaluation Advisory Committee

(a) The Medical Director shall create a Medical Evidence Evaluation Advisory Committee (MEEAC) to provide recommendations to the Medical Director on matters concerning the MTUS. The recommendations are advisory only and shall not constitute scientifically based evidence.

(1) If the Medical Director position becomes vacant, the Administrative Director shall appoint a competent person to temporarily assume the authority and duties of the Medical Director as set forth in this section, until such time that the Medical Director position is filled.

(2) The members of the MEEAC shall be appointed by the Medical Director, or his or her designee, and shall consist of 19 members of the medical community holding the following licenses: Medical Doctor (M.D.) board certified by an American Board of Medical Specialties (ABMS) approved specialty board; Doctor of Osteopathy (D.O.) board certified by an ABMS or American Osteopathic Association (AOA) approved specialty board; M.D. board certified by a Medical Board of California (MBC) approved specialty board; Doctor of Chiropractic (D.C.); Physical Therapy (P.T.); Occupational Therapy (O.T.); Acupuncture (L.Ac.); Psychology (PhD.); Doctor of Podiatric Medicine (DPM); Pharmacologist (PharmD); Nurse Practitioner (NP) or Registered Nurse (RN), and representing the following specialty fields:

(A) One member shall be from the orthopedic field;

(B) One member shall be from the chiropractic field;
(C) One member shall be from the occupational medicine field;

(D) One member shall be from the acupuncture medicine field;

(E) One member shall be from the physical therapy field;

(F) One member shall be from the psychology field;

(G) One member shall be from the pain specialty field;

(H) One member shall be from the occupational therapy field;

(I) One member shall be from the psychiatry field;

(J) One member shall be from the neurosurgery field;

(K) One member shall be from the family physician field;

(L) One member shall be from the neurology field;

(M) One member shall be from the internal medicine field;

(N) One member shall be from the physical medicine and rehabilitation field;

(O) One member shall be from the podiatrist field;

(P) One member shall be from the pharmacology field;

(Q) One member shall be from the nursing field;

(R) Two additional members shall be appointed at the discretion of the Medical Director or his or her designee.

(3) In addition to the nineteen members of MEEAC appointed under subdivision (a)(2) above, the Medical Director, or his or her designee, may appoint an additional three members to MEEAC as subject matter experts for any given topic.

(b) The Medical Director, or his or her designee, shall serve as the chairperson of MEEAC.

(c) Members of MEEAC shall make advisory recommendations to the Medical Director or his or her designee to revise, update or supplement the MTUS.

(d) The advisory MEEAC recommendations shall be supported by the best available medical evidence found in scientifically and evidenced-based medical treatment.
(e) To assess the quality and methodological rigors used to develop a medical treatment guideline, members of MEEAC shall use a modified version of the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, May 2009. The AGREE II Instrument, May 2009, consisting of 23 key items organized within six domains followed by two global rating items was found in the following website: www.agreetrust.org. A copy of the AGREE II Instrument, May 2009 version 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.

(1) Members of MEEAC shall use a modified AGREE II that uses the same six domains and two global rating items as the AGREE II Instrument, May 2009 version but includes two additional domains and additional key items:

(A) Additional domain in the modified AGREE II Instrument - Conflict of Interest

1. Key Item in this domain - All conflicts of interest of each guideline development group member were reported and discussed by the prospective group prior to the onset of his or her work.

2. Key Item in this domain - Each panel member explained how his or her conflict of interest could influence the clinical practice guideline development process or specific recommendation.

3. Key Item in this domain - The chairperson of the guideline development group had no conflicts of interest.

(B) Additional domain in the modified AGREE II Instrument - Currency of Guideline

1. Key Item in this domain - The guideline is being updated in a timely fashion (typically at least every three years and, if the guideline is more than five years old, it should be considered to be out of date).

(f) Recommendations in guidelines that have a low AGREE II overall score may still be considered, provided that the evidence supporting the recommendations is the best available medical evidence.

(g) To determine the best available medical evidence, members of MEEAC shall rank the medical evidence used to support recommendations found in either guidelines or peer-reviewed published studies by applying the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1 and shall choose the recommendations supported by the best available medical evidence.
(h) The members of MEEAC, except for the three subject matter experts, shall serve a two-year term but shall remain in that position until a successor is selected. The subject matter experts shall serve as members of the medical evidence evaluation advisory committee until the evaluation of the subject matter guideline is completed. The members of the committee shall meet as necessary, but no less than three (3) times a year.

(i) The Administrative Director, in consultation with the Medical Director, may revise, update, and supplement the MTUS as necessary.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.
Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

Section 9792.27.1. Medical Treatment Utilization Schedule (MTUS) Drug Formulary – Definitions.

For purposes of sections 9792.27.1 through 9792.27.23, the following definitions shall apply:

(a) “Administer” means the direct application of a drug or device to the body of the patient by injection, inhalation, ingestion, or other means.

(b) “Authorization through prospective review” means authorization for proposed treatment obtained through the utilization review process set forth in section 9792.6.1 et seq.

(c) “Brand name drug” means a drug that is produced or distributed under an FDA original New Drug Application (NDA) or Biologic License Application (BLA) approved by the FDA. It also includes a drug product marketed by any cross-licensed producers or distributors operating under the same NDA or BLA.

(d) “Combination drug” means a fixed dose combination of two or more active drug ingredients into a single dosage form that is FDA-approved for marketing.

(e) “Compounded drug” means any drug subject to:
(1) Article 4.5 (commencing with section 1735) or article 7 (commencing with section 1751) of division 17 of title 16 of the California Code of Regulations, or
(2) Other regulation adopted by the State Board of Pharmacy to govern the practice of compounding, or
(3) Federal law governing compounding, including title 21, United States Code, sections 353a, 353a-1, 353b.

(f) “Dispense” means: 1) the furnishing of a drug upon a prescription from a physician or other health care provider acting within the scope of his or her practice, or 2) the furnishing of drugs directly to a patient by a physician acting within the scope of his or her practice.
(g) “Executive Medical Director” means the medical director of the Division of Workers’ Compensation.

(h) “Exempt drug” means a drug on the MTUS Drug List which is designated as being a drug that does not require authorization through prospective review prior to dispensing the drug, provided that the drug is prescribed in accordance with the MTUS Treatment Guidelines. The Exempt status of a drug is designated in the column with the heading labeled “Exempt / “Exempt / Non-Exempt.”

(i) “Expedited review” means the expedited utilization review conducted prior to the delivery of the requested medical services, in accordance with Labor Code section 4610 and title 8, California Code of Regulations section 9792.6.1 et seq.

(j) “FDA” means the United States Food and Drug Administration within the United States Department of Health & Human Services.

(k) “FDA-approved drug” means a prescription or nonprescription drug that has been approved by the FDA under the federal Food, Drug, and Cosmetic Act, title 21, United States Code, section 301 et seq.

(l) “Generic drug” means a drug that is produced or distributed under an FDA Abbreviated New Drug Application (ANDA) approved by the FDA. A generic drug may be substituted for a therapeutic equivalent brand name drug pursuant to applicable state and federal laws and regulations.

(m) “MTUS Drug Formulary” means the MTUS Drug List set forth in section 9792.27.15 and the formulary rules set forth in sections 9792.27.1 through 9792.27.23.

(n) “MTUS Drug List” means the drug list and related information in section 9792.27.15, which sets forth the Exempt or Non-Exempt status of drugs listed by active drug ingredient(s).

(o) Non-Exempt drug” means a drug on the MTUS Drug List which is designated as requiring authorization through prospective review prior to dispensing the drug. The Non-Exempt Drug status of a drug is designated in the column labeled “Exempt / Non-Exempt.”

(p) “Nonprescription drug” or “over-the-counter drug” (OTC drug) means a drug which may be sold without a prescription and which is labeled for use by the consumer without the supervision of a health care professional.

(q) “Off-label use” means use of a drug for a condition, or in a dosage or method of administration, not listed in the drug’s FDA-approved labeling for approved use.

(r) “OTC Monograph” means a monograph established by the FDA setting forth acceptable ingredients, doses, formulations, and labeling for a class of OTC drugs.
(s) “Perioperative Fill” means the policy set forth in section 9792.27.13 allowing dispensing of identified Non-Exempt drugs without prospective review where the drug is prescribed within the perioperative period and meets specified criteria.

(t) “P&T Committee” means the Pharmacy and Therapeutics Committee established by the Administrative Director pursuant to Labor Code section 5307.29 to review and consult with the administrative director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs in the updating of the evidence-based drug formulary.

(u) “Physician”: Notwithstanding the definition in Labor Code section 3209.3, for purposes of the MTUS Drug Formulary, “Physician” means a medical doctor, doctor of osteopathy, or other health care provider whose scope of practice includes the prescription of drugs. However, for purposes of membership on the P&T Committee, “physician” means a medical doctor or doctor of osteopathy licensed pursuant to the California Business and Professions Code.

(v) “Prescription drug” means any drug whose labeling states “Caution: Federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import.

(w) “Prospective review” means the utilization review conducted prior to the delivery of the requested medical services, in accordance with Labor Code section 4610 and title 8, California Code of Regulations section 9792.6.1 et seq.

(x) “Special Fill” means the policy set forth in section 9792.27.12 allowing dispensing of identified Non-Exempt drugs without prospective review where the drug is prescribed or dispensed in accordance with the criteria set forth in subdivision (b) of section 9792.27.12.

(y) A “therapeutic equivalent” is a drug designated by the FDA as equivalent to a Reference Listed Drug if the two drugs are pharmaceutical equivalents (contain the same active ingredient(s), dosage form, route of administration and strength), and are bioequivalent (comparable availability and rate of absorption of the active ingredient(s).) Drugs that the FDA considers to be therapeutically equivalent products are assigned a Therapeutic Equivalence Evaluation Code beginning with the letter “A” in the FDA publication "Orange Book: Approved Products with Therapeutic Equivalence Evaluations” which is available on the FDA website and accessible via a link provided on the department’s website.

(z) “Unlisted drug” means a drug that does not appear on the MTUS Drug List and which is one of the following: an FDA-approved or a nonprescription drug that is marketed pursuant to an FDA OTC Monograph. An “unlisted drug” does not include a compounded drug but does include a combination drug.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
California Code of Regulations, title 8, sections 9792.20 et seq.

Medical Treatment Utilization Schedule regulations

Section 9792.27.2. MTUS Drug Formulary; MTUS Drug List; Scope of Coverage; Effective Date.

(a) Drugs prescribed or dispensed to treat a work related injury or illness fall within Labor Code section 4600’s definition of “medical treatment” and are subject to the relevant provisions of the MTUS, including the MTUS Treatment Guidelines, provisions relating to the presumption of correctness, and the methods for rebutting the presumption and for substantiating medical necessity where the MTUS Treatment Guidelines do not address the condition or injury.

(b) Except for continuing drug treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after January 1, 2018 for outpatient use shall be subject to the MTUS Drug Formulary, regardless of the date of injury.

(1) A drug is for “outpatient use” if it is dispensed to be taken, applied, or self-administered by the patient at home or outside of a clinical setting, including “take home” drugs dispensed at the time of discharge from a facility. “Home” includes an institutional setting in which the injured worker resides, including but not limited to, an assisted living facility.

(2) The MTUS Drug Formulary does not apply to drugs administered to the patient by a physician. However, the physician administered drug treatment is subject to relevant provisions of the MTUS, including the MTUS Treatment Guidelines.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.3. MTUS Drug Formulary Transition.

(a) Except as provided in subdivision (b), the MTUS Drug Formulary applies to drugs dispensed on or after January 1, 2018, regardless of the date of injury.

(b) (1) For injuries occurring prior to January 1, 2018, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which may include use of a Non-Exempt drug or unlisted drug, where that is necessary for the injured worker’s condition or necessary for safe weaning, tapering, or transition to a different drug.

(2) If the injured worker with a date of injury prior to January 1, 2018 is receiving a course of treatment that includes a Non-Exempt drug, an unlisted drug, or a compounded drug, the physician shall submit a progress report issued pursuant to section 9785 and a Request for Authorization that shall address the injured worker's ongoing drug treatment plan. The report shall either:

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations
(A) Include a treatment plan setting forth a medically appropriate weaning, tapering, or transitioning of the worker to a drug pursuant to the MTUS, or

(B) Provide supporting documentation, as appropriate, to substantiate the medical necessity of, and to obtain authorization for, the Non-Exempt drug, unlisted drug, or compounded drug, pursuant to the MTUS (via guidelines, Medical Evidence Search Sequence, and/or Methodology for Evaluating Medical Evidence.)

(3) The progress report, including the treatment plan and Request for Authorization provided under this subdivision, shall be submitted at the time the next progress report is due under section 9785, subdivision (f)(8), however, if that is not feasible, no later than April 1, 2018.

(4) Previously approved drug treatment shall not be terminated or denied except as may be allowed by the MTUS and in accordance with applicable utilization review and independent medical review regulations.

(5) The claims administrator shall process the progress report, treatment plan and Request for Authorization in accordance with the standard procedures and timeframes set forth in section 9792.6.1 et seq.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code. Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.4. MTUS Drug Formulary – Pharmacy Networks; Pharmacy Benefit Manager Contracts.

Where an employer or insurer contracts pursuant to Labor Code section 4600.2 with a pharmacy, a pharmacy benefit manager, or pharmacy network for the provision of drugs for the treatment of injured workers, the drugs available to the injured worker must be consistent with the MTUS Treatment Guidelines and MTUS Drug Formulary for the condition or injury being treated, and may not be restricted pursuant to the contract.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code. Reference: Sections 4600, 4600.2, 4604.5 and 5307.27, Labor Code.

Section 9792.27.5. MTUS Drug Formulary – Off-Label Use.

(a) Off-label use of a drug shall be in accordance with the MTUS Treatment Guidelines and rules and the MTUS Drug Formulary.

(b) Authorization through prospective review is not required to dispense an Exempt drug for an off-label use if the MTUS Treatment Guideline recommends the off-label use of the drug to treat the condition.
(c) Authorization through prospective review is required prior to dispensing the following drugs for an off-label use:
(1) Non-Exempt drug, or
(2) Unlisted drug, or
(3) Exempt drug lacking recommendation in the MTUS Treatment Guideline for the intended off-label use.

(d) When a physician believes it is medically necessary to prescribe a drug for an off-label use not recommended by the MTUS Treatment Guidelines or not addressed by the MTUS Treatment Guidelines, the permissibility of the treatment outside of the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical Evidence).

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.6. MTUS Drug Formulary – Access to Drugs Not Listed as an Exempt Drug on the MTUS Drug List.

(a) Drug treatment that is in conformity with the MTUS Treatment Guidelines is presumed correct on the issue of extent and scope of medical treatment pursuant to section 9792.21, subdivision (c), and Labor Code section 4604.5. Although the MTUS Drug List identifies Exempt drugs that do not require prospective review when dispensed in accordance with the MTUS Treatment Guidelines, other medically necessary drugs are available to the injured worker when authorized through prospective review.

(b) Any medically necessary FDA-approved drug, or nonprescription drug that is marketed pursuant to an FDA OTC Monograph, may be authorized through prospective review and dispensed to an injured worker if it is shown in accordance with the MTUS regulations that the drug is required to cure or relieve the injured worker from the effects of the injury. Determination of the medical necessity of treatment based on recommendations found outside of the MTUS Treatment Guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for evaluating medical evidence).

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.7. MTUS Drug Formulary – Brand Name Drugs; Generic Drugs.

If a physician prescribes a brand name drug when a less costly therapeutically equivalent generic drug exists, and writes “Do Not Substitute” or “Dispense as Written” on the

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations
prescription in conformity with Business and Professions Code section 4073, the physician must document the medical necessity for prescribing the brand name drug in the patient’s medical chart and in the Doctor’s First Report of Injury (Form 5021) or Progress Report (PR-2). The documentation must include the patient-specific factors that support the physician’s determination that the brand name drug is medically necessary. The physician must submit a Request for Authorization and obtain authorization through prospective review before the brand name drug is dispensed.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.8. Physician-Dispensed Drugs.

(a) Drugs dispensed by a physician must be authorized through prospective review prior to being dispensed, except as provided in subdivision (b), section 9792.27.12 (“Special Fill”), and section 9792.27.13 (“Perioperative Fill”).

(b) A physician may dispense up to a seven-day supply of one or more drugs that are designated as “Exempt” in the MTUS Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Treatment Guidelines and the up-to-seven-day supply is dispensed at the time of an initial visit that occurs within 7 days of the date of injury.

(c) Nothing in this Article shall invalidate a provision in a Medical Provider Network agreement which restricts physician dispensing by medical providers within the network.

(d) Nothing in this Article shall permit physician dispensing where otherwise prohibited by a pharmacy benefit contract pursuant to subdivision (a) of Labor Code section 4600.2.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.9. Compounded Drugs.

(a) Compounded drugs must be authorized through prospective review prior to being dispensed. When it is necessary for medical reasons to prescribe or dispense a compounded drug instead of an FDA-approved drug or over-the-counter drug that complies with an OTC Monograph, the physician must document the medical necessity in the patient’s medical chart, and in the Doctor’s First Report of Injury (Form 5021) or Progress Report (PR-2) and must submit a Request for Authorization. The documentation must include the patient-specific factors that support the physician’s determination that a compounded drug is medically necessary.

(b) Nothing in this Article shall invalidate a provision in a Medical Provider Network agreement which restricts physician dispensing of compounded drugs by medical providers within the network.

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations
(c) Nothing in this Article shall permit physician dispensing of compounded drugs where otherwise prohibited by a pharmacy benefit contract pursuant to subdivision (a) of Labor Code section 4600.2.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.10. MTUS Drug List; Exempt Drugs, Non-Exempt Drugs, Unlisted Drugs, Prospective Review.

(a) The MTUS Drug List is set forth by active drug ingredient(s).

(b) A drug that is identified as “Exempt” may be dispensed to the injured worker without obtaining authorization through prospective review if the drug treatment is in accordance with the MTUS Treatment Guidelines, except:
   (1) Brand name drugs are subject to section 9792.27.7;
   (2) Physician-dispensed drugs are subject to section 9792.27.8.
   (3) Compounded drugs are subject to section 9792.27.9 even if one or more of the ingredients is listed as “Exempt” on the MTUS Drug List.

(c) For a drug that is identified as “Non-Exempt,” authorization through prospective review must be obtained prior to the time the drug is dispensed. Expedited review should be conducted where it is warranted by the injured worker’s condition.

(d) For a drug that is identified as eligible for “Special Fill” or “Perioperative Fill”, the usual requirement to obtain authorization through prospective review prior to dispensing the drug is altered for the specified circumstances set forth in sections 9792.27.12 and 9792.27.13. If the requirements set forth in section 9792.27.12 or section 9792.27.13 are not met, then the drug is considered “Non-Exempt” and is subject to the provisions set forth under subdivision (c).

(e) For an unlisted drug, authorization through prospective review must be obtained prior to the time the drug is dispensed. A combination drug that is not on the MTUS Drug List is an unlisted drug even if the individual active ingredients are on the MTUS Drug List.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.11. Waiver of Prospective Review.

Nothing in the MTUS Drug Formulary shall prohibit waiver of the prospective review requirement for a Non-Exempt or unlisted drug if the drug falls within a utilization review plan’s provision of prior authorization without necessity of a request for authorization, where that provision is adopted pursuant to section 9792.7, subdivision (a)(5).

California Code of Regulations, title 8, sections 9792.20 et seq.
Medical Treatment Utilization Schedule regulations
Section 9792.27.12. MTUS Drug List – Special Fill.

(a) The MTUS Drug List identifies drugs that are subject to the Special Fill policy. Under this policy, a drug that usually requires prospective review because it is “Non-Exempt” will be allowed without prospective review as specified in subdivision (b).

(b) The drug identified as a Special Fill drug may be dispensed to the injured worker without seeking prospective review if all of the following conditions are met:

(1) The drug is prescribed at the single initial treatment visit following a workplace injury, provided that the initial visit is within 7 days of the date of injury; and

(2) The prescription is for a supply of the drug not to exceed the limit set forth in the MTUS Drug List; and

(3) The prescription for the Special Fill – eligible drug is for:

(A) An FDA-approved generic drug or single source brand name drug, or,

(B) A brand name drug where the physician documents and substantiates the medical need for the brand name drug rather than the FDA-approved generic drug, and

(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines.

(c) When calculating the 7-day period in subdivision (b)(1), the day after the date of injury is “day one.”

(d) An employer or insurer that has a contract with a pharmacy, pharmacy network, pharmacy benefit manager, or a medical provider network (MPN) that includes a pharmacy or pharmacies within the MPN, may provide for a longer Special Fill period or may cover additional drugs under the Special Fill policy pursuant to a pharmacy benefit contract or MPN contract.

(e) After the Special Fill provision has been in effect for one year, the Administrative Director shall evaluate the impact of the provision on the use of opioids by injured workers. As part of the evaluation process, the Administrative Director shall solicit feedback from the workers’ compensation system participants.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.
Section 9792.27.13. MTUS Drug List – Perioperative Fill.

(a) The MTUS Drug List identifies drugs that are subject to the Perioperative Fill policy. Under this policy, the Non-Exempt drug identified as a Perioperative Fill drug may be dispensed to the injured worker without seeking prospective review if all of the following conditions are met:

(1) The drug is prescribed during the perioperative period; and

(2) The prescription is for a supply of the drug not to exceed the limit set forth in the MTUS Drug List; and

(3) The prescription for the Perioperative Fill - eligible drug is for:

(A) An FDA-approved generic drug or single source brand name drug, or,

(B) A brand name drug where the physician documents and substantiates the medical need for the brand name drug rather than the FDA-approved generic drug, and

(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines.

(b) For purposes of this section, the perioperative period is defined as the period from 4 days prior to surgery to 4 days after surgery, with the day of surgery as “day zero”.

(c) An employer or insurer that has a contract with a pharmacy, pharmacy network, pharmacy benefit manager, or a medical provider network that includes a pharmacy or pharmacies within the MPN, may provide for a longer Perioperative Fill period or may cover additional drugs under the Perioperative Fill policy pursuant to a pharmacy benefit contract or MPN contract.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code. Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.14. Treatment Provided Under Applicable Health and Safety Regulations.
The MTUS Drug Formulary and associated regulations do not relieve an employer of any responsibilities pursuant to applicable health and safety regulations such as the requirements of the California occupational Bloodborne Pathogens standard at title 8, California Code of Regulations, section 5193, including the responsibility to provide urgent post-exposure prophylaxis as needed to protect the health of the employee.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code. Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.
Section 9792.27.15. MTUS Drug List.

[Excel Document: MTUS DRUG LIST (8 CCR §9792.27.15)]

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.16. National Drug Codes, Unique Pharmaceutical Identifier - MTUS Drug List.

(a) The Administrative Director may maintain and post on the DWC website a listing by National Drug Code, RxCUI (clinical drug concept unique identifier maintained by the National Library of Medicine), or other unique pharmaceutical identifier, of drug products that are embodied in the MTUS Drug List. If posted, the listing will be regularly updated to account for revisions to the MTUS Drug List and for changes in drug products that are marketed for outpatient use.

(b) For each active ingredient on the MTUS Drug List, the product listing shall include brand name and therapeutically equivalent generic versions of outpatient prescription drugs and non-prescription drug products. The listing shall include only drug products that can be self-administered by the patient. Injectable drug products must be packaged and identified for patient self-administration.

(c) The listing shall include combination drugs with multiple active ingredients only if the combination of active ingredients is listed on the MTUS Drug List.

(d) The listing may include, but is not limited to, the following data elements:
   (1) National Drug Code, RxCUI, or other pharmaceutical identifier;
   (2) Drug ingredient(s);
   (3) Therapeutic class;
   (4) Strength;
   (5) Dosage form;
   (6) Exempt or Non-Exempt status, as applicable;
   (7) Any applicable Special Fill or Perioperative Fill policies.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section 9792.27.17. Formulary – Dispute Resolution.

(a) Medical Necessity Disputes.
Disputes over the medical necessity of pharmaceutical treatment covered by the MTUS Drug Formulary are governed by the utilization review and independent medical review provisions of Labor Code sections 4610, 4610.5, and regulations at section 9792.6.1 et seq, and section 9792.10.1 et seq.
(b) Formulary Rule Medical Treatment Disputes Other than Medical Necessity Disputes. Disputes over failure to follow formulary rules, other than medical necessity disputes covered by subdivision (a), shall be resolved through the procedure for non-IMR/IBR disputes set forth in WCAB rules, title 8, California Code of Regulations, section 10451.2, Determination of Medical Treatment Disputes.

Authority: Sections 133, 4603.5, 5307.3, 5307.1 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.1, 5307.27 and 5307.29, Labor Code.

Section 9792.27.18. Pharmacy and Therapeutics Committee – Composition; Application for Appointment; Term of Service.

(a) The Administrative Director shall create an independent Pharmacy and Therapeutics Committee (P&T Committee) to review and consult with the Administrative Director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs, for purposes of updating the MTUS Drug List.

(b) The P&T Committee shall consist of the Executive Medical Director, and six members appointed by the Administrative Director.

(1) The Executive Medical Director, or his or her designee, shall serve as chairperson of the P&T Committee. If the Executive Medical Director position becomes vacant, the Administrative Director shall appoint a competent person to temporarily assume the authority and duties of the Executive Medical Director on the P&T Committee, until such time that the Executive Medical Director position is filled.

(2) The Administrative Director shall appoint 3 pharmacists and 3 physicians (medical doctors or doctors of osteopathy) to serve on the P&T Committee. At least one of the physicians appointed shall be actively engaged in the treatment of injured workers. At least one of the pharmacists appointed shall be an actively practicing pharmacist.

(3) The members of the P&T Committee shall be appointed to serve a two-year term, but shall remain in the position until a successor is appointed. A member may apply to be reappointed when his or her two-year term ends. The Administrative Director may cancel the appointment of a committee member if a substantial conflict of interest arises, or for other reason constituting good cause.

(c) A person interested in serving on the P&T Committee shall submit an application on the form prescribed by the Administrative Director and a completed Conflict of Interest Disclosure Form. The applicant for P&T Committee appointment shall demonstrate that he or she has knowledge or expertise in one or more of the following:

(1) Clinically appropriate prescribing of covered drugs;

(2) Clinically appropriate dispensing and monitoring of covered drugs;
(3) Drug use review;

(4) Evidence-based medicine.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section 9792.27.19. Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form.

[FORM: DWC MTUS PT-App (New 7/17)]

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section 9792.27.20. Pharmacy and Therapeutics Committee – Conflict of Interest.

(a) The conflict of interest standards are intended to ensure that the members of the P&T Committee are free from financial interests or other relationships that could compromise the objectivity of the members of the committee as they perform their duties to consult with the Administrative Director on formulary updates based upon the principles of evidence-based medicine. Appointed members of the P&T Committee must impartially perform formulary update review activities, and must be free of conflicts of interest.

(b) Persons applying to be appointed to the P&T Committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or a company engaged in the development of a pharmaceutical formulary for commercial sale, and shall not have been so employed for 12 months prior to the appointment. A P&T Committee member who undertakes such employment during the term of appointment shall not be eligible to continue to serve on the committee.

(c) Members of the P&T Committee shall not have a substantial financial conflict of interest in relation to a pharmaceutical entity.

(1) “Pharmaceutical entity” means a pharmaceutical manufacturer, pharmaceutical repackager, pharmaceutical relabeler, compounding pharmacy, pharmacy benefits management company, biotechnology company, or any other business entity that is involved in manufacturing, packaging, selling or distribution of prescription or non-prescription drugs, drug delivery systems, or biological agents.

(2) For purposes of this section, “substantial financial conflict of interest” means that the applicant or committee member, or his or her immediate family member, has a direct or indirect financial interest in a pharmaceutical entity, including:
(A) Receipt of income within the previous 12 months, amounting to a total of $500 or more from the pharmaceutical entity, including but not limited to salary, wages, speaking fees, consultant fees, expert witness fees, honoraria, gifts, loans, and travel payments;

(B) Receipt of grants or research funding from the pharmaceutical entity within the previous 24 months;

(C) Has had ownership interest in the pharmaceutical entity at any time during the previous 12 months, including but not limited to, a sole proprietorship, partnership, limited liability company, or stock ownership in a corporation that is not publicly traded;

(D) Investment interest worth $2,000 or more in a publicly-traded pharmaceutical entity, not including an investment held through a diversified mutual fund;

(3) “Immediate family member” means spouse, domestic partner, child, son-in-law, daughter-in-law, parent, mother-in-law, father-in-law, brother or sister;

(4) (A) “Direct financial interest” means an interest held by the applicant or committee member.
(B) “Indirect financial interest” means an interest held by the applicant or committee member’s immediate family member, or held by a business entity or trust in which the applicant or committee member owns directly or indirectly, or beneficially, a 10-percent interest or greater.

(d) The members of the P&T Committee shall submit an updated Conflict of Interest Disclosure Form annually, and more frequently if there have been changes in circumstances relating to employment by, or financial interests in, a pharmaceutical entity.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section 9792.27.21. Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form.

[FORM: DWC MTUS PT-COI (New 7/17)]

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section 9792.27.22. Pharmacy and Therapeutics Committee – Meetings.

(a) The P&T Committee shall meet when deemed necessary by the Executive Medical Director, but no less frequently than quarterly.
(b) P&T Committee meetings shall be conducted in accordance with the Bagley-Keene Open Meeting Act, California Government Code sections 11120 through 11132.

(c) Notice of the regularly scheduled meetings shall be given at least ten days in advance of the meeting as follows:

(1) To persons who have requested notice of the meetings;

(2) To persons on the Administrative Director’s mailing list; and

(3) By posting notice on the division’s website.

(d) The Executive Medical Director shall include a period to receive public comment during the P&T Committee meetings, in a manner consistent with the orderly and efficient conduct of the business of the committee. Members of the public addressing the P&T Committee shall be limited to three minutes per speaker.

(e) The Executive Medical Director shall maintain a written summary of the meetings and the recommendations made to the Administrative Director in a format determined by the Administrative Director. The written summary shall be posted on the Division’s website. It shall include a description of any action taken and the vote or abstention of each P&T Committee member present.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.

Section 9792.27.23. MTUS Drug List Updates.

(a) The Administrative Director shall consult with the P&T Committee as needed on updates to the MTUS Drug List, which may be adopted by the Administrative Director on a quarterly or more frequent basis in order to allow provision for all appropriate medications.

(b) The P&T Committee is responsible for reviewing and consulting with the Administrative Director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs. In carrying out these duties the P&T Committee may provide consultation on a variety of relevant issues, including but not limited to the following:

(1) Recommendations on prospective review requirements for drugs;

(2) Recommendations on Special Fill and Perioperative Fill designation and policies;

(3) Review of drug treatment changes adopted into the MTUS Treatment Guidelines to identify needed additions or deletions of drugs from the MTUS Drug List;
(4) Recommendations on establishing a therapeutic interchange program in order to promote safe and appropriate cost effective care.

(c) The P&T Committee serves in an advisory role only. P&T Committee recommendations are not binding on the Administrative Director.

(d) Updates to the MTUS Drug List will be adopted by issuance of an Administrative Director’s order specifying the changes and the effective date, and shall be posted on the division’s website pursuant to Labor Code section 5307.29.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code. Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.