

TITLE 8. INDUSTRIAL RELATIONS
DIVISION 1. DEPARTMENT OF INDUSTRIAL RELATIONS
CHAPTER 4.5. DIVISION OF WORKERS' COMPENSATION
SUBCHAPTER 1. ADMINISTRATIVE DIRECTOR -- ADMINISTRATIVE RULES
ARTICLE 5.5.2 MEDICAL TREATMENT UTILIZATION SCHEDULE

§ 9792.20. Medical Treatment Utilization Schedule—Definitions

As used in this Article:

(a) “American College of Occupational and Environmental Medicine (ACOEM)” is a medical society of physicians and other health care professionals specializing in the field of occupational and environmental medicine, dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education.

(b) “ACOEM Practice Guidelines” means the American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines, 2nd Edition (2004). A copy may be obtained from the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org).

(c) “Chronic pain” means any pain that persists beyond the anticipated time of healing.

(d) “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.

(e) ~~“Evidence based Evidence Based Medicine” means based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE.~~ means a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values.

(f) ~~“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 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.~~

(gf) “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.

(hg) “Medical treatment guidelines” means 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.

(ih) “MEDLINE” is the largest component of PubMed, the U.S. National Library of Medicine’s database of biomedical citations and abstracts that is searchable on the Web. Its website address is www.pubmed.gov.

(ji) “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; or currently adopted for use by one or more U.S. state governments or by the U.S. federal government; and is the most current version.

(kj) “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).

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

(l) “Scientifically based” means based on scientific literature, wherein the body of literature is identified through performance of a literature search ~~in MEDLINE~~, the identified literature is evaluated, and then used as the basis for the guideline.

(m) “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 intended to assist in the provision of medical treatment by offering an analytical framework for the evaluation and treatment of injured workers and to help those who make decisions regarding the medical treatment of injured workers understand what treatment has been proven effective in providing the best medical outcomes to those workers, in accordance with section 4600 of the Labor Code. The MTUS provides a framework for the most effective treatment of injured and ill workers and is based on the principles of Evidence Based Medicine (EBM). EBM is a systematic approach to making~~

clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community 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 strength of evidence used to support the recommendations of a medical condition. The best available evidence is then used to guide clinical decision making. In order to effectively promote health and well-being, health care professionals shall base clinical decisions on evidenced based medicine.

(c) Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence based, peer-reviewed, medical treatment guidelines that are nationally recognized by the medical community, in accordance with subdivisions (b) and (e) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10. The MTUS shall constitute best practice guidelines for the provision of medical care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions. The MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the MTUS for the duration of the medical condition.

(d) The MTUS is inapplicable in the following two situations. First, the MTUS is inapplicable when the MTUS' presumption of correctness is successfully rebutted. Second, the MTUS is inapplicable when the MTUS is silent and does not address a medical condition or diagnostic test.

(1) The MTUS' presumption of correctness may be rebutted if medical evidence is cited that contains a recommendation directly applicable to the specific medical condition or diagnostic test requested by the injured worker and is supported by a higher level of evidence than the medical evidence used to support the MTUS' recommendation.

(e) When the MTUS is inapplicable, medical care shall be in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines and/or peer-reviewed published studies that are nationally recognized by the medical community.

(f) To determine the best available medical evidence, the strength of evidence methodologies set forth in sections 9792.25.2 and 9792.25.3 shall apply.

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. Presumption of Correctness, Burden of Proof and Strength of Evidence Definitions.

(a) ~~The MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the MTUS for the duration of the medical condition. 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.~~

(b) ~~For all conditions or injuries not addressed by the MTUS, 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.~~

(c)(1) ~~For conditions or injuries not addressed by either subdivisions (a) or (b) above; for medical treatment and diagnostic services at variance with both subdivisions (a) and (b) above; or where a recommended medical treatment or diagnostic service covered under subdivision (b) is at variance with another treatment guideline also covered under subdivision (b), the following ACOEM's strength of evidence rating methodology is adopted and incorporated as set forth below, and shall be used to evaluate scientifically based evidence published in peer reviewed, nationally recognized journals to recommend specific medical treatment or diagnostic services:~~

~~(A) Table A—Criteria Used to Rate Randomized Controlled Trials~~

~~Studies shall be rated using the following 11 criteria. Each criterion shall be rated 0, 0.5, or 1.0, thus the overall ratings range from 0-11. A study is considered low quality if the composite rating was 3.5 or less, intermediate quality if rated 4-7.5, and high quality if rated 8-11.~~

Criteria	Rating Explanation
<p>Randomization: Assessment of the degree that randomization was both reported to have been performed and successfully* achieved through analyses of comparisons of variables between the two groups.</p> <p>*Simply allocating individuals to groups</p>	<p>Rating is “0” if the study is not randomized or reports that it was and subsequent analyses of the data/tables suggest it either was not randomized or was unsuccessful.</p> <p>Rating is “0.5” if there is mention of randomization and it appears as if it was performed, however there are no data on the success of randomization, it appears incomplete, or other questions about randomization cannot be adequately addressed.</p> <p>Rating is “1.0” if randomization is specifically stated and data reported on subgroups suggests that the study did achieve successful randomization.</p>

<p>does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful.</p>	
<p>Treatment Allocation Concealed: Concealment of the allocation scheme from all involved, not just the patient.</p>	<p>Rating is “0” if there is no description of how members of the research team or subjects would have not been able to know how they were going to receive a particular treatment, or the process used would not be concealed.</p> <p>Rating is “0.5” if the article mentions how allocation was concealed, but the concealment was either partial involving only some of those involved or other questions about it are unable to be completely addressed.</p> <p>Rating is “1.0” if there is a concealment process described that would conceal the treatment allocation to all those involved.</p>
<p>Baseline Comparability: Measures how well the baseline groups are comparable (e.g., age, gender, prior treatment).</p>	<p>Rating is “0” if analyses show that the groups were dissimilar at baseline or it cannot be assessed.</p> <p>Rating is “0.5” if there is general comparability, though one variable may not be comparable.</p> <p>Rating is “1.0” if there is good comparability for all variables between the groups at baseline.</p>
<p>Patient Blinded</p>	<p>Rating is “0” if there is no mention of blinding of the patient.</p> <p>Rating is “0.5” if it mentions blinding, but the methods are unclear.</p> <p>Rating is “1.0” if the study reports blinding, describes how that was carried out, and would plausibly blind the patient.</p>
<p>Provider Blinded</p>	<p>Rating is “0” if there is no mention of blinding of the provider.</p>

	<p>Rating is “0.5” if it mentions blinding, but the methods are unclear.</p> <p>Rating is “1.0” if the study reports blinding, describes how that was carried out and would plausibly blind the provider.</p>
Assessor Blinded	<p>Rating is “0” if there is no mention of blinding of the assessor.</p> <p>Rating is “0.5” if it mentions blinding, but the methods are unclear.</p> <p>Rating is “1.0” if the study reports blinding, describes how that was carried out and would plausibly blind the assessor.</p>
Controlled for Co-interventions: The degree to which the study design controlled for multiple interventions (e.g., a combination of stretching exercises and anti-inflammatory medication or mention of not using other treatments during the study).	<p>Rating is “0” if there are multiple interventions or no description of how this was avoided.</p> <p>Rating is “0.5” if there is brief mention of this potential problem.</p> <p>Rating is “1.0” if there is a detailed description of how co-interventions were avoided.</p>
Compliance Acceptable: Measures the degree of non-compliance.	<p>Rating is “0” if there is no mention of non-compliance.</p> <p>Rating is “0.5” if non-compliance is briefly addressed and the description suggests that there was compliance, but a complete assessment is not possible.</p> <p>Rating is “1.0” if there are specific data and the non-compliance rate is less than 20%.</p>
Dropout Rate: Measures the drop out	<p>Rating is “0” if there is no mention of drop-outs or it cannot be inferred from the data presented.</p>

<p>rate.</p>	<p>Rating is “0.5” if the drop-out issue is briefly addressed and the description suggests that there were few drop-outs, but a complete assessment is not possible.</p> <p>Rating is “1.0” if there are specific data and the drop-out rate is under 20%.</p>
<p>Timing of Assessments: Timing rates the timeframe for the assessments between the study groups.</p>	<p>Rating is “0” if the timing of the evaluations is different between the groups.</p> <p>Rating is “0.5” if the timing is nearly identical (e.g., one day apart).</p> <p>Rating is “1.0” if the timing of the assessments between the groups is identical.</p>
<p>Analyzed by Intention to Treat: This rating is for whether the study was analyzed with an intent to treat analysis.</p>	<p>Rating is “0” if it was not analyzed by intent to treat.</p> <p>Rating is “0.5” if there is not mention of intent to treat analysis, but the results would not have been different (e.g., there was nearly 100% compliance and no drop-outs).</p> <p>Rating is “1.0” if the study specifies analyses by intention to treat.</p>
<p>Lack of Bias: This rating does not enter into the overall rating of an article. This is an overall indication of the degree to which biases are felt to be present in the study.</p>	<p>Rating is “0” if there are felt to be significant biases that are uncontrolled in the study and may have influenced the study’s results.</p> <p>Rating is “0.5” if there are felt to be some biases present, but the results are less likely to have been influenced by those biases.</p> <p>Rating is “1.0” if there are few biases, or those are well controlled and unlikely to have influenced the study’s results.</p>

(B) Table B—Strength of Evidence Ratings

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 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.

A	Strong evidence base: One or more well conducted systematic reviews or meta analyses, or two or more high quality studies.
B	Moderate evidence base: At least one high quality study, a well-conducted systematic review or meta-analysis of lower quality studies or multiple lower quality studies relevant to the topic and the working population.
C	Limited evidence base: At least one study of intermediate quality.
I	Insufficient Evidence: Evidence is insufficient or irreconcilable.

(2) Evidence shall be given the highest weight in the order of the strength of evidence.

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

(1) “Bias” means any tendency to influence the results of a trial (or their interpretation) other than the experimental intervention. Biases include inadequate generation of the randomization sequence, inadequate concealment of allocation, selection, confounding, lack of blinding, selective outcome reporting, failure to do intention-to-treat analysis, early stopping, selection, and publication.

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

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

(4) “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.

(5) “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.

(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) “Cohort study” (also known as Follow-up 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.

(8) “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.

(9) “Confounding variable” means extrinsic factor associated with the exposure under study and cause of the outcome.

(10) “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.

(11) “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.

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

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

(14) “Expert opinion” means a determination by an expert, through a process of evidenced-based thinking that a given practice should or should not be labeled evidenced based, and published in a peer-reviewed medical journal.

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

(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) “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 analyzed together as representing that treatment arm, 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.

(18) “Low risk of bias” means those trials or studies that contain methodological safeguards to protect against biases related to generation of the randomization sequence, concealment of allocation, selection, blinding, selective outcome reporting, early stopping, and intention to treat.

(19) “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 than not to be true. A meta-analysis may be part of a systematic review or may be performed in the absence of a systematic review.

(20) “Post-marketing surveillance” means a procedure implemented after a drug has been licensed for public use, 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.

(21) “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.

(22) “Prospective study” (also known as Follow-up or Cohort 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 prospective 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.

(23) “Randomized trial” means a clinical experiment in which subjects in a population are randomly allocated 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 rigorous 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.

(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 increase 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. Process to Determine When Medical Care is Reasonable and Necessary

(a) Pursuant to Labor Code section 4600 the employer shall provide medical care that is reasonably required to cure or relieve the injured employee from the effects of his or her injury.

(b) The MTUS is the standard for the provision of medical care in accordance with Labor Code section 4600. However, in situations when the MTUS is inapplicable, medical care shall be in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines and/or peer-reviewed published studies that are nationally recognized by the medical community.

(c) When the MTUS is inapplicable, a medical literature search shall be conducted by those providers making treatment decisions, including the requesting provider and

medical reviewers, to find medical evidence that is directly applicable to the injured worker's specific medical condition. Recommendations found in the medical treatment guideline and/or peer-reviewed published study that support and/or oppose the treatment or diagnostic service requested by the injured worker shall be cited.

(d) The cited recommendations shall be evaluated using EBM-based principles as set forth in sections 9792.25.2 and 9992.25.3 to determine which recommendation is supported with the best available medical evidence. Medical care that is reasonably necessary to cure or relieve the injured worker from the effects of his or her injury shall be in accordance with the recommendation supported with the best available medical evidence.

(e) Where there is a discrepancy between the recommendations of two different medical treatment guidelines or peer-reviewed published studies, the following framework to evaluate the strength of evidence used to support the differing recommendations shall apply:

(1) Medical Treatment Guidelines: Where there is a discrepancy between the recommendations of two medical treatment guidelines, the strength of evidence methodology set forth in section 9792.25.2 shall be used to determine the highest quality medical treatment guideline.

(2) Peer-reviewed Published Studies: Where there is a discrepancy between the recommendations of two peer-reviewed published studies, the strength of evidence methodology set forth in §9792.25.3 shall be used to determine the highest quality peer-reviewed published study.

(3) Medical Treatment Guidelines vs. Published Study: Medical treatment guidelines contain citations of studies used to support its recommendations. However, there are peer-reviewed studies that are scientifically based and published in journals that are nationally recognized by the medical community that have not been used to support a medical treatment guideline recommendation. Where there is a discrepancy between the recommendation in a medical treatment guideline and the recommendation of a published study that is not part of a medical treatment guideline, the strength of evidence methodology set forth in §9792.25.3 shall be used to determine the highest quality published study. The studies used to support the medical treatment guideline recommendation shall be evaluated against the peer-reviewed published study that has not been used to support a guideline recommendation.

(f) In the interest of efficiency and consistency, when conducting the medical literature search of the large body of available medical evidence, the following search sequence shall be followed:

(1) Search the most current version of ACOEM and/or ODG and choose the recommendation that is supported by the highest level of evidence according to the

strength of evidence methodology set forth in section 9792.25.3; if no relevant recommendations are found or if the current version is more than three years old then,

(2) Search the most current version of workers' compensation medical guidelines established by one or more US state governments or by the US federal government; if no relevant recommendations are found or if the current version is more than three years old then,

(3) Search other evidenced based medical treatment guidelines that are recognized by the national medical community and are scientifically based. Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: www.guideline.gov; if no relevant recommendations are found or if the current version is more than three years old then,

(4) Search for studies that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community. 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.

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

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

§ 9792.25.2 Strength of Evidence - Method for Evaluating the quality of Medical Treatment Guidelines

(a) To evaluate the quality of a medical treatment guideline the modified Appraisal of Guideline for Research & Evaluation (AGREE) II medical guideline evaluation tool shall be applied.

(b) The modified AGREE II consists of 27 key items organized within 8 domains followed by 2 global rating items. Each domain captures a unique dimension of guideline quality.

(1) Each of the 27 key items shall be scored from 1 to 7, with 1 indicating strong disagreement with the statement expressed in the item and 7 indicating strong agreement with the statement expressed in the item. A score of 1 would be appropriate if there is no information or if the concept is very poorly reported, whereas a score of 7 would be warranted if the quality of the reporting is exceptional. Scores between 2 and 6 represent how close the reporting is to these two extremes.

(2) An overall score is then calculated for each of the eight domains. In order to do this, the total item scores for all of the items are summed. The scaled domain score is calculated in the following manner:

Scaled domain score =

$$\frac{\text{Obtained score} - \text{minimum possible score}}{\text{Maximum possible score} - \text{minimum possible score}}$$

The minimum possible score is 1 for each item and the maximum possible score is 7 for each item. If multiple reviewers are used, the minimum and maximum possible scores are the obtained score multiplied by the number of reviewers. The scaled domain score, when converted to a percentage by multiplying the final result by 100%, represents how close to perfect the score for that domain was.

(3) The guideline with the highest percentage score shall be used as the source to approve or deny a treatment or diagnostic service recommendation.

(A) Although the application of the AGREE II medical guideline evaluation tool leads to a percentage score, the figure may slightly vary between reviewers because individual judgments are still required. Therefore, the percentage scores calculated by any reviewer shall remain confidential and will not be disclosed in the decision.

(c) The eight (8) domains and 27 key items of the modified AGREE II are as follows:

(1) Domain One - Scope and Purpose: is concerned with the overall aim of the guideline, the specific health questions, and the target population.

(A) Item 1. The overall objective(s) of the guideline is (are) specifically described.

(B) Item 2. The health question(s) covered by the guideline is (are) specifically described.

(C) Item 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

(2) Domain Two – Stakeholder Involvement: focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users.

(A) Item 4. The guideline development group includes individuals from all relevant professional groups.

(B) Item 5. The views and preferences of the target population (patients, public, etc.) have been sought.

(C) Item 6. The target users of the guideline are clearly defined.

(3) Domain Three – Rigor of Development: relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them.

(A) Item 7. Systematic methods were used to search for evidence.

(B) Item 8. The criteria for selecting the evidence are clearly described.

(C) Item 9. The strengths and limitations of the body of evidence are clearly described.

(D) Item 10. The methods for formulating the recommendations are clearly described.

(E) Item 11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

(F) Item 12. There is an explicit link between the recommendations and the supporting evidence.

(G) Item 13. The guideline has been externally reviewed by experts prior to its publication.

(H) Item 14. A procedure for updating the guideline is provided.

(4) Domain Four – Clarity of Presentation: deals with the language, structure, and format of the guideline.

(A) Item 15. The recommendations are specific and unambiguous.

(B) Item 16. The different options for management of the condition or health issue are clearly presented.

(C) Item 17. Key recommendations are easily identifiable.

(5) Domain Five – Applicability: pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying the guideline.

(A) Item 18. The guideline describes facilitators and barriers to its application.

(B) Item 19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

(C) Item 20. The potential resource implications of applying the recommendations have been considered.

(D) Item 21. The guideline presents monitoring and/or auditing criteria.

(6) Domain Six – Editorial Independence: is concerned with the formulation of recommendations not being unduly biased with competing interests.

(A) Item 22. The views of the funding body have not influenced the content of the guideline.

(B) Item 23. Competing interests of guideline development group members have been recorded and addressed.

(7) Domain Seven – Conflict of Interest: is concerned with a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

(A) Item 24. All conflicts of interest of each guideline development group member were reported and discussed by the prospective development group prior to the onset of his or her work.

(B) Item 25. Each panel member explained how his or her conflict of interest could influence the clinical practice guideline development process or specific recommendation.

(C) Item 26. The chairperson of the guideline development group had no conflict of interest.

(8) Domain Eight – Currency of Guideline: is concerned with how recently the guideline was developed or the timeliness of the guideline updates.

(A) Item 27. The guideline is being updated in a timely fashion (typically at least every 3 years and, if the guideline is more than 5 years old, it should be considered to be out of date).

(d) After each of the 27 items are reviewed and scored, an assessment of the entire guideline shall be made as follows:

(1) The first step is an overall assessment of the quality of the guideline and represents a subjective assessment, again scored from 1 (lowest quality) to 7 (highest quality).

(2) The second step in the assessment is the recommendation regarding using the guideline and will result in one of three possibilities:

(A) Recommending the guideline for use as it is;

(B) Recommending the guideline for use with modifications; or

(C) Not recommending the guideline for use.

(g) If a guideline is recommended as “Yes” or “Yes with modifications”, then it may be considered a source to approve or deny medical treatment recommendations on a given medical condition.

(h) If a guideline is recommended as a “no” it should not be used as the source to approve or deny a medical treatment recommendation. However, the individual recommendations in this guideline may still be used as the source to approve or deny a medical treatment recommendation. The original studies supporting the individual recommendation must be evaluated using the process described in section 9792.25.3.

(i) The Modified AGREE II Worksheet for the Evaluation of Medical Guidelines is set forth in Appendix A and may be used when applying the Modified AGREE II medical evaluation tool.

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

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

Appendix A to Section 9792.25.2.

THE MODIFIED AGREE II WORKSHEET FOR THE EVALUATION OF MEDICAL GUIDELINES

Domain 1. Scope and purpose

Item 1. The overall objective(s) of the guideline is (are) specifically described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 2. The health question(s) covered by the guideline is (are) specifically described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 2. Stakeholder involvement

Item 4. The guideline development group includes individuals from all relevant professional groups

<u>1</u> Strongly disagree	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> Strongly agree
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Comments:

Item 5. The views and preferences of the target population (patients, public, etc.) have been sought

<u>1</u> Strongly disagree	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> Strongly agree
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Comments:

Item 6. The target users of the guideline are clearly defined

<u>1</u> Strongly disagree	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> Strongly agree
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Comments:

Domain 3. Rigor of development

Item 7. Systematic methods were used to search for evidence

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 8. The criteria for selecting the evidence are clearly described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 9. The strengths and limitations of the body of evidence are clearly described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 10. The methods for formulating the recommendations are clearly described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 11. The health benefits, side effects, and risks have been considered in formulating the recommendations

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 12. There is an explicit link between the recommendations and the supporting evidence

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 13. The guideline has been externally reviewed by experts prior to its publication

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 14. A procedure for updating the guideline is provided

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 4. Clarity of presentation

Item 15. The recommendations are specific and unambiguous

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 16. The different options for management of the condition or health issue are clearly presented

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 17. Key recommendations are easily identifiable

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 5. Applicability

Item 18. The guideline describes facilitators and barriers to its application

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 19. The guideline provides advice and/or tools on how the recommendations can be put into practice

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 20. The potential resource implications of applying the recommendations have been considered

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 21. The guideline presents monitoring and/or auditing criteria

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 6. Editorial independence

Item 22. The views of the funding body have not influenced the content of the guideline

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 23. Competing interests of guideline development group members have been recorded and addressed

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 7. Conflict of interest

Item 24. All conflicts of interest of each guideline development group member were reported and discussed by the prospective development group prior to the onset of his or her work

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 25. Each panel member explained how his or her conflict of interest could influence the clinical practice guideline development process or specific recommendation

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 26. The chairperson of the guideline development group had no conflicts of interest

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 8. Currency of guideline

Item 27. The guideline is being updated in a timely fashion (typically at least every 3 years and, if the guideline is more than 5 years old, it should be considered to be out of date)

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Overall guideline assessment

1. Rate the overall quality of this guideline

<u>1</u> <u>Lowest possible quality</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Highest possible quality</u>
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Comments:

2. I would recommend this guideline for use

Yes

Yes, with modifications

No

Comments:

§ 9792.25.3 Strength of Evidence - Method for Evaluating the Quality of Evidence used to Support Studies Published in the Medical and Scientific Literature

(a) To evaluate the quality of evidence used to support a study published in the medical or scientific literature, the DWC/MTUS Hierarchy of Evidence for Different Clinical Question as set forth in section 9792.25(b) shall be applied as follows:

(1) Determine if the study is directly applicable to the specific medical condition or diagnostic test requested by the injured worker. Direct applicability refers to the extent to which the individual patients, workers, or subjects, interventions, and outcome measures are similar to the injured worker and his or her specific medical condition or diagnostic service request. A study published in the medical or scientific literature that is not directly applicable to the specific medical condition or diagnostic test requested by the injured worker if it evaluates a different population, setting, or intervention should not be used as the source to approve or deny a medical treatment recommendation unless a directly applicable study is not available. If directly applicable studies are not available, the population most similar to the injured worker should be used and the reasoning documented.

(2) Determine the design used to support the original study. Study designs are categorized as follows:

(A) Systematic Review of:

1. Randomized Control Trial
2. Prospective or Cohort Studies

(B) Randomized Control Trial

(C) Observational studies:

1. Prospective study or Cohort Study
2. Cross-sectional study
3. Case-control study
5. Case-series
6. Uncontrolled or observational study
7. Case report

D. Published expert opinion

(3) Determine the study quality used to support the original study. Factors to consider include, but are not limited to, the methodological safeguards to protect against biases related to the generation of the randomization sequence, concealment of allocation, blinding, selective outcome reporting, early stopping, and intention to treat. A study that is determined to be of poor quality due to the presence of these factors shall not be used as justification for a medical treatment decision.

(4) Answer the four clinical questions in the Hierarchy of Evidence for Different Clinical Questions as set forth in Section 9792.25.4 and apply the corresponding hierarchy of evidence. The four clinical questions are as follows:

(A) 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.

(B) 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.

(C) 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.

(D) 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.

(5) The levels of evidence are listed from highest to lowest, as defined by the principles of Evidence Based Medicine, in each Clinical Question category. 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. The level of evidence for each published study (e.g. 1a, 1b, 2, etc.) shall be documented and included with the citation.

(A) When relying on lower levels of evidence, documentation shall be provided that higher levels of evidence are absent.

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

DWC/MTUS Hierarchy of Evidence for Different Clinical Questions

<u>Evidence Level</u>	<u>Treatment Benefits</u> How useful is Treatment X in treating patients with Disease Y?	<u>Diagnostic Test</u> How useful is Test X in diagnosing patients with Disease Y?	<u>Prognosis</u> What will happen to a patient with Disease Y if nothing is done?	<u>Treatment Harms</u> What are the harms of intervention (treatment or diagnostic test) X in patients with Disease Y?
1a	<u>Systematic review of low risk of bias randomized trials</u>	<u>Systematic review of high-quality prospective studies (homogeneous sample of patients, consecutively enrolled, all undergoing the index test and reference standard) or systematic review of low risk of bias randomized control trial with low risk bias</u>	<u>Systematic review of inception cohort studies or of control arms of low risk of bias randomized trials</u>	<u>Systematic review of randomized trials with low risk of bias</u>
1b	<u>Randomized trial with low risk of bias</u>	<u>High-quality prospective study or cohort study or randomized control trial with low risk of bias</u>	<u>Inception cohort study or control arm from one randomized trial with low risk of bias</u>	<u>Randomized trials with low risk of bias</u>
1c	<u>One or more randomized trials with identified risks of bias (or systematic review of such trials)</u>	<u>Biased cross-sectional study</u>	<u>Cohort study or control arm of randomized trial with identified risks of bias</u>	<u>Prospective study</u>
2	<u>Non-randomized cohort studies that include controls</u>	<u>Case-control study enrolling a broad spectrum of patients and controls with conditions that may be confused</u>	<u>Case-series or case control studies</u>	<u>Randomized trial(s) with identified risk of bias</u>

		<u>with the disease being considered</u>		
<u>3</u>	<u>Case-control studies or historically controlled studies</u>	<u>Case-control study using severe cases and healthy controls</u>		<u>Non-randomized controlled cohort/follow-up study (post-marketing surveillance)</u>
<u>4</u>	<u>Uncontrolled studies (case studies or case reports)</u>		<u>Uncontrolled studies (observational studies, case studies, or case reports)</u>	<u>Consistent 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)</u>
<u>5</u>	<u>Published expert opinion</u>	<u>Published expert opinion</u>	<u>Published expert opinion</u>	<u>Toxicological or mechanistic data that demonstrate or support biologic plausibility</u>

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

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

§ 9792.26. Medical Evidence Evaluation Advisory Committee

(a)(1) The Medical Director shall create a medical evidence evaluation advisory committee to provide recommendations to the Medical Director on matters concerning the MTUS. The recommendations are advisory only and shall not constitute scientifically based evidence.

(A) 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 medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of 17 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.); ~~or~~ Doctor of Podiatric Medicine (DPM); Pharmacologist (PharmD); Nurse Practitioner (NP) or Registered Nurse (RN) or equivalent, 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;
- (PR) Two additional members shall be appointed at the discretion of the Medical Director or his or her designee.

(3) In addition to the ~~seventeen~~ nineteen members of the medical evidence evaluation advisory committee appointed under subdivision (a)(2) above, the Medical Director, or

his or her designee, may appoint an additional three members to the medical evidence evaluation advisory committee as subject matter experts for any given topic.

(b) The Medical Director, or his or her designee, shall serve as the chairperson of the medical evidence evaluation advisory committee.

(c) To evaluate evidence when making recommendations to revise, update or supplement the MTUS, the members of the medical evidence evaluation advisory committee shall:

(1) Apply the strength of evidence methodology as set forth in requirements of subdivision (b) of section 9792.25 section 9792.25.2 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community to evaluate the quality of medical treatment guidelines.

(2A) Apply the ACOEM's strength of evidence rating methodology to the scientific evidence as set forth in subdivision (c) of section 9792.25 after identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of section 9792.25; Recommendations in guidelines that have a low AGREE II overall score may still be used provided that the evidence used to support the recommendations are the best available medical evidence. To determine the best available medical evidence, the strength of evidence methodology set forth in section 9792.25.3 shall apply.

(2) Apply the strength of evidence methodology as set forth in section 9792.25.3 to determine the highest quality peer-reviewed published study.

(3) Apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed by the Administrative Director, as set forth in subdivision (c) of section 9792.25.

(d) The members of the medical evidence evaluation advisory committee, except for the three subject matter experts, shall serve a term of two year period, 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 ~~four (4)~~ three (3) times a year.

(e) 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.