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*~~*a*) "ACOEM ~~*Practice Guidelines*~~" 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.*~~, 2nd Edition (2004). A copy~~ *ACOEM guidelines* 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*~~*b*) "Chronic pain" means ~~*any pain that persists beyond the anticipated time of healing*~~ *pain lasting three or more months from the initial onset of pain.*

(~~*d*~~*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.

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

(~~*f*~~*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~~ evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to sections 9789.10-9789.111~~ medical evaluation and treatment; 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 *reviewed and updated within the last five years.*

~~*(i) "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.*~~

(*jh*) "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.

(*ki*) "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).

(~~kl~~*j*) "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.

(~~lm~~*k*) "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 to support a recommendation. ~~for the guideline.~~

(~~mn~~*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; Medical Literature Search Sequence

(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 work-related illness or injury to achieve functional improvement, return-to-work, and disability prevention.

(c) Evidence-Based Medicine (EBM) is a systematic approach to making clinical decisions which allows the integration of the best available research 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 strength of evidence used to support the recommendations for 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 EBM.

(~~c~~d) ~~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 (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10.~~ The MTUS is based on the principals of EBM. The *recommended guidelines set forth in the* MTUS ~~*is*~~ *are* presumptively correct on the issue of extent and scope of medical treatment and diagnostic services for the duration of *a* ~~*the*~~ medical condition. ~~*The MTUS*~~ *and* shall constitute the standard for the provision of medical care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions.

(e) ~~*The MTUS does not address every medical condition or diagnostic test and the MTUS's presumption of correctness may be successfully rebutted*~~*. When the MTUS's presumption of correctness is challenged pursuant to Labor Code section 4604.5 or when there is a topical gap and a medical treatment or a diagnostic test is not addressed by the recommended guidelines set forth in the MTUS, medical care shall be in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed published studies that are nationally recognized by the medical community.*

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

~~*(f) When the MTUS is silent on a particular medical condition or diagnostic test or when the MTUS is successfully rebutted, medical care shall be in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed published studies that are nationally recognized by the medical community.*~~

(f) To find the best available medical evidence requires a search of the large body of medical literature. Conducting a comprehensive medical literature search is resource-intensive. Therefore, in the interest of efficiency and consistency, the medical literature search sequence set forth in subdivision 9792.21(g) shall be sufficient and applies to the following physicians:

(1) Treating physicians may apply the medical literature search sequence set forth in subdivision 9792.21(g) to find a recommendation that supports their Request for Authorization;

(2) Utilization Review physicians shall apply the medical literature search sequence set forth in subdivision 9792.21(g) if the requesting treating physician cited a recommendation in the chart notes or Request for Authorization and the requested treatment or diagnostic service is being denied;

(3) Independent Medical Review physicians shall apply the medical literature search sequence set forth in subdivision 9792.21(g) to ensure that medical care is in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed studies that are nationally recognized by the medical community.

~~*(g) In situations described in subdivision (f), a medical literature search shall be conducted by medical reviewers making treatment decisions and should be conducted by the requesting provider, to find the recommendation supported with the highest level of evidence applicable to the injured worker's specific medical condition.*~~

~~*(h) Conducting a comprehensive medical literature search is resource intensive. Providers making treatment decisions may conduct a comprehensive medical literature search, but for purposes of this section and in the interest of efficiency and consistency, the medical literature search sequence set forth in subdivision (i) shall be sufficient.*~~

~~*(i) When conducting a medical literature search of the large body of available medical evidence, the following search sequence, at a minimum, shall be followed:*~~

(g) Medical literature search sequence to find the best available medical evidence:

(1) Search the most current version of ACOEM or ODG to find a recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. If the current version *of ACOEM or ODG* is more than five years old, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then

(2) 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 specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: www.guideline.gov/. If the current version *of the medical treatment guideline* is more than five years old, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then

(3) Search for current studies, ~~*five years old or less*~~ 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 specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology 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.

(~~*j*~~*h*) After ~~*conducting a*~~ *applying the* medical literature search *sequence set forth in section 9792.21(g),* Utilization Review decisions and Independent Medical Review decisions shall contain the citation of the medical treatment guideline or peer-reviewed published study with the recommendation supported with the highest level of evidence. Treating physicians may cite the medical treatment guideline or peer-reviewed published study that contains the recommendation supported with the highest level of evidence in the chart notes or Request for Authorization, particularly if barriers to getting authorization are anticipated.

(1) The citation shall include, at a minimum, information that clearly identifies the source of the recommendation.

(~~*k*~~*i*) Finally, if there is a discrepancy between the recommendations cited, the underlying medical evidence supporting the differing recommendations shall be evaluated according

to the *MTUS Hierarchy of Evidence for Different Clinical Questions* ~~*strength of evidence methodology*~~ set forth in section 9792.25.1 to determine which recommendation is supported with the highest level of 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.*~~

(1) Utilization Review physicians shall apply the MTUS Hierarchy of Evidence for Different Clinical Questions if the treating physician cited a recommendation in the chart notes or Request for Authorization and the requested treatment or diagnostic service is being denied. In these situations, Utilization Review decisions shall clearly document the levels of evidence as set forth in the MTUS Hierarchy of Evidence for Different Clinical Questions (e.g. 1a, 1b, 2, etc.) between the recommendation cited by the treating physician and the recommendation used to deny the treatment or diagnostic service request.

(2) Independent Medical Review physicians shall apply the MTUS Hierarchy of Evidence for Different Clinical Questions if there is a dispute between the recommendations cited by the treating physician and the Utilization Review physician or if the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed studies that are nationally recognized by the medical community was not cited by either the treating physician or the Utilization Review physician and the IMR reviewer is able to cite a recommendation supported with stronger medical evidence. In these situations, the Independent Medical Review decisions shall clearly document the levels of evidence as set forth in the MTUS Hierarchy of Evidence for Different Clinical Questions (e.g. 1a, 1b, 2, etc.) for all recommendations cited including any recommendations cited by the Independent Medical Review physician. The Independent Medical Review decision shall contain the recommendation supported with the best available medical evidence which determines medical care that is reasonably necessary to cure or relieve the injured worker from the effects of his or her injury.

(j) Employers, 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 unique medical circumstances warranting an exception. The treating physician shall provide clear documentation of the clinical rationale focusing on 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, and 5307.27, Labor Code.

§ 9792.25. ~~Presumption of Correctness, Burden of Proof and Strength of Evidence~~ 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**
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. *Simply allocating individuals to groups does not constitute sufficient grounds to	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. 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. Rating is "1.0" if randomization is specifically stated and data reported on subgroups suggests that the study did achieve successful randomization.

assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful.	
Treatment Allocation Concealed: Concealment of the allocation scheme from all involved, not just the patient.	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. 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. Rating is "1.0" if there is a concealment process described that would conceal the treatment allocation to all those involved.
Baseline Comparability: Measures how well the baseline groups are comparable (e.g., age, gender, prior treatment).	Rating is "0" if analyses show that the groups were dissimilar at baseline or it cannot be assessed. Rating is "0.5" if there is general comparability, though one variable may not be comparable. Rating is "1.0" if there is good comparability for all variables between the groups at baseline.
Patient Blinded	Rating is "0" if there is no mention of blinding of the patient. Rating is "0.5" if it mentions blinding, but the methods are unclear. Rating is "1.0" if the study reports blinding, describes how that was carried out, and would plausibly blind the patient.
Provider Blinded	Rating is "0" if there is no mention of blinding of the provider.

	~~Rating is "0.5" if it mentions blinding, but the methods are unclear.~~ ~~Rating is "1.0" if the study reports blinding, describes how that was carried out and would plausibly blind the provider.~~
~~**Assessor Blinded**~~	~~Rating is "0" if there is no mention of blinding of the assessor.~~ ~~Rating is "0.5" if it mentions blinding, but the methods are unclear.~~ ~~Rating is "1.0" if the study reports blinding, describes how that was carried out and would plausibly blind the assessor.~~
~~**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).~~	~~Rating is "0" if there are multiple interventions or no description of how this was avoided.~~ ~~Rating is "0.5" if there is brief mention of this potential problem.~~ ~~Rating is "1.0" if there is a detailed description of how co-interventions were avoided.~~
~~**Compliance Acceptable:** Measures the degree of non-compliance.~~	~~Rating is "0" if there is no mention of non-compliance.~~ ~~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.~~ ~~Rating is "1.0" if there are specific data and the non-compliance rate is less than 20%.~~
~~**Dropout Rate:** Measures the drop-out~~	~~Rating is "0" if there is no mention of drop-outs or it cannot be inferred from the data presented.~~

rate.	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. Rating is "1.0" if there are specific data and the drop-out rate is under 20%.
Timing of Assessments: Timing rates the timeframe for the assessments between the study groups.	Rating is "0" if the timing of the evaluations is different between the groups. Rating is "0.5" if the timing is nearly identical (e.g., one day apart). Rating is "1.0" if the timing of the assessments between the groups is identical.
Analyzed by Intention to Treat: This rating is for whether the study was analyzed with an intent to treat analysis.	Rating is "0" if it was not analyzed by intent to treat. 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). Rating is "1.0" if the study specifies analyses by intention to treat.
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.	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. 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. Rating is "1.0" if there are few biases, or those are well controlled and unlikely to have influenced the study's results.

(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) "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 AGREE II Instrument can be found in~~* 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 their interpretation) other than the experimental intervention. Biases include but are not limited to vested interests such as financial interests, academic interests, industry influence, confounding, 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, selection, 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 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 Strength of Evidence - Method for Evaluating the Quality of Evidence used to Support a Recommendation; MTUS Hierarchy of Evidence for Different Clinical Questions

(a) To evaluate the quality of evidence used to support a recommendation found in a medical treatment guideline or in a study published in the medical or scientific literature, the MTUS Hierarchy of Evidence for Different Clinical Questions as set forth in section 9792.25.1(b) shall be applied as follows:

(1) Determine if the recommendation is applicable to the specific medical *treatment* ~~*condition*~~ or diagnostic test requested by the injured worker. Applicability refers to the extent to which the individual patients, workers, subjects, interventions, and outcome measures are similar to the injured worker and his or her specific medical condition or diagnostic service request. If a recommendation evaluates a different population, setting, or intervention, it should not be used as the source to approve or deny a medical treatment request. The recommendation that evaluates a population, setting or intervention most similar to the injured worker should be used and the reasoning documented.

(2) Determine what factors, if any, bias may have had in the study used to support a recommendation. 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 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.

(3) Determine the design of the study used to support the recommendation. Study designs are categorized as follows:

(A) Systematic Review of:

1. Randomized Controlled Trials

2. Prospective or Cohort Studies

(B) Randomized Controlled Trials

(C) Observational studies:

1. Prospective study or Cohort Study

2. Cross-sectional study

3. Case-control study

4. Case-series

5. Uncontrolled or observational study

6. Case report

(D) Published expert opinion

(4) 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:

(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) 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.

(A) The level of evidence for each published study (e.g. 1a, 1b, 2, etc.) shall be documented and included with the citation.

(B) 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

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

		conditions that may be confused with the disease being considered		
3	Case-control studies or historically controlled studies	Case-control study using severe cases and healthy controls		Non-randomized controlled cohort/follow-up study (post-marketing surveillance)
4	Uncontrolled studies (case studies or case reports)		Uncontrolled studies (observational studies, case studies, or case reports)	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/For Industry/DataStandards/ IndividualCaseSafety Reports/default.htm
5	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, and 5307.27, Labor Code.

§ 9792.26. Medical Evidence Evaluation Advisory Committee

(a)~~(1)~~ The Medical Director shall create a ~~m~~Medical ~~e~~Evidence ~~e~~Evaluation ~~a~~Advisory ~~e~~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.

(~~A~~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 ~~medical evidence evaluation advisory committee~~ MEEAC 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;

(~~P~~R) 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~~ MEEAC 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~~ MEEAC 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~~ MEEAC.

(c) ~~To evaluate evidence when making recommendations to revise, update or supplement the MTUS, the members of the medical evidence evaluation advisory committee shall~~: Members of MEEAC shall make advisory recommendations to the Medical Director or his or her designee to revise, update or supplement the MTUS.

~~(1) Apply the requirements of subdivision (b) of section 9792.25 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidenced-based, and nationally recognized by the medical community to evaluate the quality of medical treatment guidelines.~~

~~(2) 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;~~

~~(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 advisory MEEAC recommendations shall be supported by the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed published studies that are nationally recognized by the medical community.

(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 ~~*and can be*~~ *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 ~~*original*~~ 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 strength of evidence methodology set forth in section 9792.25.2 and shall choose the recommendations supported by the best available medical evidence.

(~~d~~h) The members of ~~the medical evidence evaluation advisory committee~~ MEEAC, except for the three subject matter experts, shall serve a two-year 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~~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.