

**RULES
OF
TENNESSEE DEPARTMENT OF LABOR AND WORKFORCE DEVELOPMENT
WORKERS' COMPENSATION DIVISION**

**CHAPTER 0800-02-25
WORKERS' COMPENSATION MEDICAL TREATMENT GUIDELINES**

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0800-02-25.01 PURPOSE AND SCOPE.

- (1) Purpose: To provide guidelines for the diagnosis and treatment of commonly occurring workers' compensation injuries.
- (2) Scope: To include guidelines for diagnostic and treatment requests including pharmaceuticals and pain management.

Authority: T.C.A. § 50-6-124. **Administrative History:** Original rule filed November 30, 2015; effective February 28, 2016.

0800-02-25-.02 DEFINITIONS.

- (1) "Act" means the applicable Workers' Compensation Law in effect.
- (2) "Administrator" means the chief administrative officer of the Tennessee Bureau of Workers' Compensation, or the Administrator's designee.
- (3) "Authorized Treating Physician" means the practitioner chosen from the panel required by T.C.A. § 50-6-204, or a practitioner who has received a referral from the original authorized treating physician if the employer has not provided an alternative referral within three business days. "Authorized Treating Physician" also means any practitioner specifically authorized by the employer.
- (4) "Bureau" means the Tennessee Bureau of Workers' Compensation attached for administrative purposes to the Tennessee Department of Labor and Workforce Development.
- (5) "Employee" means an employee as defined in T.C.A. § 50-6-102, but also includes the employee's representative or legal counsel.
- (6) "Employer" means an employer as defined in T.C.A. § 50-6-102, but also includes an employer's insurer, third party administrator, self-insured employers, self-insured pools and trusts, as well as the employer's representative or legal counsel, as applicable.
- (7) "Health care provider" includes, but is not limited to, the following: licensed individual chiropractic physician, dentist, physical therapist, physician, physician assistant, optometric physician, podiatrist, surgeon, occupational therapist, group of practitioners, hospital, free standing surgical outpatient facility, health maintenance organization, industrial or other clinic, occupational healthcare center, home health agency, visiting nursing association, laboratory, medical supply company, community mental health center, pharmacist/pharmacy, and any other facility or entity providing treatment or health care services for a work-related injury.

(Rule 0800-02-25-.02, continued)

- (8) "Medical Director" means the Medical Director of the Tennessee Bureau of Workers' Compensation appointed by the Administrator pursuant to T.C.A. § 50-6-126, or the Medical Director's designee.
- (9) "Medically necessary" or "medical necessity" means healthcare services, including medications, that a physician (or other healthcare provider acting within their scope of practice), exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
 - (a) In accordance with generally accepted standards of medical practice; and
 - (b) Clinically appropriate, in terms of type, frequency, extent, site and duration; and considered effective for the patient's illness, injury or disease. Treatment primarily for the convenience of the patient, physician, or other healthcare provider does not constitute medical necessity.
- (10) "Treatment guideline" means the Institute of Medicine (2011) definition of a "clinical practice guideline": "statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefit and harms of alternative care options."
- (11) "Utilization review" means evaluation of the necessity, appropriateness, efficiency and quality of medical care services, including the prescribing of one (1) or more Schedule II, III, or IV controlled substances for pain management for a period of time exceeding ninety (90) days from the initial prescription of such controlled substances, provided to an injured or disabled employee based on medically accepted standards and an objective evaluation of those services provided; provided, that "utilization review" does not include the establishment of approved payment levels, a review of medical charges or fees, or an initial evaluation of an injured or disabled employee by a physician specializing in pain management;
 - (a) "Utilization review" does not include elective requests for clarification of coverage, referrals, consultations, second opinions from medical providers, or office visits.
 - (b) "Utilization review" does not include analysis of or opinions regarding medical causation or compensability.

Authority: T.C.A. §§ 50-6-102, 50-6-122, 50-6-124, 50-6-126, 50-6-233, 56-6-703, and 56-61-102.

Administrative History: Original rule filed November 30, 2015; effective February 28, 2016.

0800-02-25-.03 TREATMENT GUIDELINES.

- (1) Effective January 1, 2016, the Tennessee Bureau of Workers' Compensation adopts the current edition, and any future published updates, of the Work Loss Data Institute ODG Guidelines as published by the Work Loss Data Institute, the Chronic Pain Guidelines of the State of Tennessee, Department of Health, and any other related appendices to the above-referenced guidelines adopted by the Administrator.
- (2) Medical treatment provided by or at the direction of the authorized treating physician, or other healthcare provider, in accordance with the ODG Guidelines, Chronic Pain Guidelines of the State of Tennessee, Department of Health, and any other related appendices to the Guidelines adopted by the Administrator in effect at the date the treatment is recommended, listed in section (1) above is presumed to be reasonable and necessary. Any utilization review of treatment must apply the ODG Guidelines listed in section (1) above, in determining whether treatment is medically necessary. Any treatment that explicitly follows the treatment

(Rule 0800-02-25-.03, continued)

guidelines adopted by the administrator or is reasonably derived therefrom, including allowances for specific adjustments to treatment, shall have a presumption of medical necessity for utilization review purposes. This presumption shall be rebuttable only by clear and convincing evidence that the treatment erroneously applies the guidelines or that the treatment presents an unwarranted risk to the injured worker.

- (3) It is recognized that each individual clinical situation and patient is unique. The guidelines are not a standard or a mandate. Exceptions to and the proper application of the guidelines require judgment. The Utilization Review and prior approval/authorization procedures and timeframes remain in effect. See Utilization Review Rule 0800-02-06. A mechanism for the timely appeal for these exceptional situations is set forth in Rule 0800-02-06-.07 Appeals.
- (4) The employer shall not deny treatment based solely on the determination that the treatment falls outside of the guideline if such denial is not supported by documented evidence-based medicine.
 - (a) If a provider makes a written request by fax or e-mail (and receives acknowledgement of receipt of the request) for authorization for a treatment at least 21 business days in advance of the anticipated date that treatment is to be delivered and has not been notified in writing or confirmed telephone call or confirmed fax at least 7 business days in advance of the date of the proposed treatment, it is presumed to be medically necessary, a covered service, and to be paid for by the employer.
 - (b) If a provider makes a verbal request for authorization, the burden of proof for showing that authorization was granted by the employer rests with the provider.
- (5) The employer shall not be responsible for charges for medical treatment that is not in accord with the guidelines unless:
 - (a) it was provided in a medical emergency,
 - (b) it was authorized by the employer,
 - (c) it was approved through the appeal process by the Bureau.
- (6) As new information becomes available, the Administrator may direct the Medical Director to publish or post on the Division's website, advisory or explanatory updates or bulletins to the guidelines. Print copies will be made available by request to the Medical Director. The Medical Advisory Committee may be consulted at the Administrator's discretion.
- (7) As of January 1, 2016, physicians and other providers dispensing drugs required to be reported in the Tennessee Controlled Substances Monitoring Database (CSMD) from their offices or clinics must report these medications in the Tennessee Controlled Substances Monitoring Database (CSMD) within one business day of the dispensing of those medications. These provisions are in accord with T.C.A. § 53-10-305, T.C.A. § 53-10-307 and T.C.A. § 53-10-310 as amended.

Authority: T.C.A. §§ 50-6-122, 50-6-124, 50-6-126, and 50-6-233. **Administrative History:** Original rule filed November 30, 2015; effective February 28, 2016.

0800-02-25-.04 DRUG FORMULARY.

- (1) The purpose of the drug formulary is to facilitate the safe and appropriate use of medications for injured workers, and is a specific part of the Treatment Guidelines set forth in subsection .03 of this rule.

(Rule 0800-02-25-.04, continued)

- (2) The Bureau adopts the ODG Drug Formulary as found in Drug Appendix A published and updated by the Work Loss Data Institute.
- (3) Prescriptions presented to a pharmacy from an authorized provider and appropriate for the prescribed injury within seven (7) days of an alleged or accepted workers' compensation claim may be filled for a maximum of seven (7) days, even if the prescribed medication is status "N." The employer is responsible for the payment.
- (4) The Formulary shall be made available by posting on the Bureau's website. Subsequent updates shall be effective on the first day of the month following posting of an update on the Bureau's website.
- (5) Drugs identified with the status "N" in the current edition of the ODG/Appendix A, and any other related appendices adopted by the Administrator in effect at the date the treatment is recommended, shall require prior approval. An "N" drug should not be approved unless its use in a particular case is supported by documentation of evidence-based medicine.
- (6) Compounded medications and topical applications are "N" and subject to prior approval. An "N" drug should not be approved unless its use in a particular case is supported by documentation of evidence-based medicine.
- (7) Prescriptions for "Y" drugs should be filled without delay if they are approved as appropriate for the nature of the injury being treated.
- (8) For compensation claims with a date of injury (DOI) on or after January 1, 2016, and for new medication prescriptions for dates of injury prior to January 1, 2016, the formulary applies to all drugs that are prescribed or dispensed for outpatient use on or after six-months following the effective date of these rules.
- (9) For refill prescriptions and medications being used for dates of injury (DOI) before January 1, 2016, the formulary applies to all drugs that are prescribed or dispensed for outpatient care one year from the effective date of these rules.
- (10) Retrospective review of medications will be allowed only for drugs that are not appropriate for the injured worker's diagnosis. Only the next refill prescribed by the authorized treating physician can be denied.
- (11) The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:
 - (a) "Closed Formulary" means all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, and applies to the categories listed below that require prior approval:
 1. drugs identified with a status of "N" in the current edition of the Official Disability Guidelines Treatment in Workers' Compensation (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates;
 2. any compound or topical; and
 3. any investigational or experimental drug that has not yet been identified as a "Y" or "N" drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet accepted as the prevailing standard of care.

(Rule 0800-02-25-.04, continued)

- (b) "Compounding", "compound" or "compounded" medication or preparation means the preparation, mixing, assembling, packaging, or labeling of a drug or device:
 - 1. as the result of a practitioner's prescription drug order based on the practitioner-patient-pharmacist relationship in the course of professional practice;
 - 2. for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;
 - 3. in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or
 - 4. for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing.
- (c) "Evidence-based ", medicine" (EBM) means an approach to medical practice intended to optimize decision-making by emphasizing the use of evidence from well-designed and well- conducted research, to include the integration with clinical expertise and patient values and an evolutionary progression of knowledge based on the basic and clinical sciences.
- (d) "Initial Prescription" means the beginning, starting, commencing or first written order for a medication. Changes in dosage, addition of or removal of previously prescribed medications either individually or in combination are not considered an initial prescription.
- (e) "Medical emergency" means the sudden onset of a medical condition manifested by acute symptoms of sufficient severity, including severe pain that in the absence of immediate medical attention could reasonably be expected to result in:
 - 1. Placing the patient's health or bodily functions in serious jeopardy; or
 - 2. Serious dysfunction of any body organ or part.
- (f) "Nonprescription drug" or "over-the-counter medication" means a non-narcotic drug that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law.
- (g) "Open Formulary" means all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but does not include drugs that lack FDA approval, or non-drug items.
- (h) "Prescribing Doctor" means a physician or dentist who prescribes prescription drugs or over the counter medications in accordance with the physician's or dentist's license and state and federal laws and rules. For purposes of this chapter, prescribing doctor includes an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders, who prescribes prescription drugs or over the counter medication under the physician's supervision and in accordance with the health care practitioner's license and state and federal laws and rules.

(Rule 0800-02-25-.04, continued)

- (i) "Prescription" means an order for a prescription or nonprescription drug to be dispensed, in accordance with the applicable federal definition and in T.C.A. Title 53 Chapter 10.
 - (j) "Prescription drug" means:
 - 1. A substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;
 - 2. A drug that under federal law is required, before being dispensed or delivered, to be labeled with the statement: "Caution: federal law prohibits dispensing without prescription;" "Rx only;" or another legend that complies with federal law; or
 - 3. A drug that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a prescribing doctor only.
 - (k) "Substitution" means the dispensing of a drug or a brand of drug other than the drug or brand of drug ordered or prescribed.
 - (l) "Topical" means a prescription substance or substances, not injected or ingested, that are used on the skin or other membranes, or are applied to exterior or exposed surfaces. This category includes "inhalers."
- (12) The provider may appeal to the Bureau's Medical Director for an expedited decision, using a request for an expedited determination.
- (a) The purpose of this section is to provide a prescribing doctor or pharmacy the ability to obtain an expedited determination from the Bureau's Medical Director in instances where a denial of a previously prescribed and dispensed drug(s) for the workers' compensation injury poses an unreasonable risk of a medical emergency as defined in this title.
 - (b) The request for an expedited determination from the Medical Director may be rejected at the sole discretion of the Medical Director if it does not contain the following information:
 - 1. Injured employee name;
 - 2. Date of birth of injured employee;
 - 3. The injured employee's Social Security Number.
 - 4. Tennessee Bureau of Workers' Compensation state file or claim number;
 - 5. Date of injury;
 - 6. Prescribing doctor's name;
 - 7. Prescribing doctor's DEA number;
 - 8. Name of drug and dosage;
 - 9. Requestor's name (pharmacy or prescribing doctor);
 - 10. Requestor's contact information;

(Rule 0800-02-25-.04, continued)

11. A statement that the prior approval request for a previously prescribed and dispensed drug(s), which is excluded from the Closed Formulary, has been denied by the insurance carrier, accompanied by the denial letter if available;
 12. A statement that an independent review request or request for reconsideration has already been submitted to the insurance carrier or the insurance carrier's utilization review agent;
 13. A statement that the prior approval denial poses an unreasonable risk of a medical emergency and justification from a medical perspective such as withdrawal potential or other significant side effects or complications;
 14. A statement that the potential medical emergency has been documented in the prior approval process;
 15. A statement of justification from a medical perspective of the potential medical emergency such as withdrawal potential or other significant side effects or complications;
 16. A statement that the insurance carrier has been notified that a request for an expedited determination is being submitted to the Bureau; and
 17. The signature of the requestor and the following certification by the requestor for paragraphs 10 to 14 of this subsection, "I hereby certify under penalty of law that the previously listed conditions have been met."
- (c) A request for an expedited determination under this section shall be processed and approved by the Medical Director of the Bureau in accordance with this section. At the discretion of the Medical Director of the Bureau, an incomplete request or a request with incomplete information for an expedited determination under this section may be considered in accordance with this section.
- (d) The request for an expedited determination may be submitted on the designated form available on the Bureau of Workers' Compensation website. In the event the Bureau form is not available, the written request should contain the provisions of subsection (b) of this section.
- (e) The requestor shall provide a copy of the request to the insurance carrier, prescribing doctor, injured employee, and dispensing pharmacy, if known, on the date the request is submitted to the Bureau.
- (f) An expedited determination shall be effective retroactively to the date of the original prescription.
- (13) A request for reconsideration of a prior approval denial is not required prior to a request for an expedited determination under this section. If, within 15 business days from the initial prior approval denial, a request for reconsideration or an expedited determination request is not initiated within 15 business days by the provider to the employer, carrier or utilization review agent and an expedited determination request is not communicated by the provider to the Medical Director of the Bureau at that time, then the opportunity to request an expedited determination under this section does not apply. Additionally, where a health care provider has sought relief from a previous adverse determination by requesting reconsideration by the employer, carrier, or utilization review agent and also by requesting an expedited

(Rule 0800-02-25-.04, continued)

determination by the Medical Director, the determination of the Medical Director shall prevail over the reconsideration determination of the employer, carrier, or utilization review agent.

- (14) If pursuing an expedited determination after denial of a reconsideration request, a complete request shall be submitted within five business days of the notification of the reconsideration denial.
- (a) An appeal of the utilization review organization decision relating to the medical necessity and reasonableness of the drugs contained in the expedited determination shall be submitted in accordance with these rules.
 - (b) The Medical Director's determination shall continue in effect until the later of:
 - 1. Final determination of a medical dispute regarding the medical necessity and reasonableness of the drug;
 - 2. Expiration of the period for a timely appeal; or
 - 3. Agreement of the parties.
 - (c) Withdrawal of the request for an expedited determination by the requestor constitutes acceptance of the prior approval denial.
 - (d) All parties shall comply with an expedited determination issued in accordance with this section and the insurance carrier shall reimburse the pharmacy or other payer for prescriptions dispensed in accordance with the determination of the Medical Director.
 - (e) The insurance carrier shall notify the prescribing doctor, injured employee, and the dispensing pharmacy once reimbursement is no longer required because of the denial by the Medical Director of a request for an expedited determination.
 - (f) A decision issued by a utilization review organization is not a Bureau decision.
 - (g) A party may seek to reverse or modify the Medical Director's determination issued under this section if:
 - 1. A final determination of medical necessity has been rendered; and
 - 2. The party requests a hearing in accordance with the procedures of the Court of Workers' Compensation Claims.
 - 3. The insurance carrier may dispute the request for expedited determination or the Medical Director's determination entered under this title by filing a written request for a hearing in accordance with the Court of Workers' Compensation Claims procedures.

Authority: T.C.A. § 50-6-124. **Administrative History:** Original rule filed November 30, 2015; effective February 28, 2016.