

CHAPTER 134: BENEFITS – GUIDELINES FOR MEDICAL SERVICES, CHARGES, AND PAYMENTS

Title 28 Texas Administrative Code (TAC) § 134.500, § 134.530 and § 134.540

§134.500. Definitions.

(a) The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

- (1) Brand name drug--A drug marketed under a proprietary, trademark-protected name.
- (2) Certified workers' compensation health care network (certified network)--An organization that is certified in accordance with Insurance Code Chapter 1305 and department rules.
- (3) Closed formulary--All available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but excludes:
 - (A) drugs identified with a status of "N" in the current edition of the Official Disability Guidelines Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates;
 - (B) ~~any prescription drug created through compounding [any compound that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates]; and~~
 - (C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined in Labor Code §413.014(a).
- (4) Compounding--As defined under Occupations Code §551.003(9), the preparation, mixing, assembling, packaging, or labeling of a drug or device:
 - (A) as the result of a practitioner's prescription drug order based on the practitioner-patient-pharmacist relationship in the course of professional practice;
 - (B) 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;
 - (C) in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or
 - (D) for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing, except as allowed under Occupations Code §562.154 or Occupations Code

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- (5) Generic--See generically equivalent in definition of paragraph (6) of this section.
- (6) Generically equivalent--As defined under Occupations Code §562.001, a drug that, when compared to the prescribed drug, is:
- (A) pharmaceutically equivalent--Drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendia or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium; and
 - (B) therapeutically equivalent--Pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.
- (7) Medical emergency--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:
- (A) placing the patient's health or bodily functions in serious jeopardy; or
 - (B) serious dysfunction of any body organ or part.
- (8) Nonprescription drug or over-the-counter medication--A non-narcotic drug that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law.
- (9) Open formulary--Includes 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.
- (10) Prescribing doctor--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, under Occupations Code Chapter 157, 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.
- (11) Prescription--An order for a prescription or nonprescription drug to be dispensed.
- (12) Prescription drug--
- (A) A substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;
 - (B) 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

(C) 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.

(13) Statement of medical necessity--A written statement from the prescribing doctor to establish the need for treatments or services, or prescriptions, including the need for a brand name drug where applicable. A statement of medical necessity shall include:

(A) the injured employee's full name;

(B) date of injury;

(C) social security number;

(D) diagnosis code(s);

(E) whether the drug has previously been prescribed and dispensed, if known, and whether the inability to obtain the drug poses an unreasonable risk of a medical emergency; and

(F) how the prescription treats the diagnosis, promotes recovery, or enhances the ability of the injured employee to return to or retain employment.

(14) Substitution--As defined under Occupations Code §551.003(41), the dispensing of a drug or a brand of drug other than the drug or brand of drug ordered or prescribed.

(b) This section will become effective for all drugs that are prescribed and dispensed for outpatient use on or after MM/DD/YY (intended to be a date certain approximately sixty days after the rule amendment is finally adopted).

§134.530. Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks.

(a) Applicability. The closed formulary applies to all drugs that are prescribed and dispensed for outpatient use for claims not subject to a certified network on or after September 1, 2011 when the date of injury occurred on or after September 1, 2011.

(b) Preauthorization for claims subject to the Division's closed formulary.

(1) Preauthorization is only required for:

(A) drugs identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates;

(B) ~~any prescription drug created through compounding [any compound that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates];~~ and

(C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined in Labor Code §413.014(a).

(2) When §134.600(p)(12) of this title (relating to Preauthorization, Concurrent Review, and Voluntary Certification of Health Care) conflicts with this section, this section prevails.

(c) Preauthorization of intrathecal drug delivery systems.

(1) An intrathecal drug delivery system requires preauthorization in accordance with §134.600 of this title and the preauthorization request must include the prescribing doctor's drug regime plan of care, and the anticipated dosage or range of dosages for the administration of pain medication.

(2) Refills of an intrathecal drug delivery system with drugs excluded from the closed formulary, which are billed using Healthcare Common Procedure Coding System (HCPCS) Level II J codes, and submitted on a CMS-1500 or UB-04 billing form, require preauthorization on an annual basis. Preauthorization for these refills is also required whenever:

(A) the medications, dosage or range of dosages, or the drug regime proposed by the prescribing doctor differs from the medications, dosage or range of dosages, or drug regime previously preauthorized by that prescribing doctor; or

(B) there is a change in prescribing doctor.

(d) Treatment guidelines. Except as provided by this subsection, the prescribing of drugs shall be in accordance with §137.100 of this title (relating to Treatment Guidelines), the division's adopted treatment guidelines.

(1) Prescription and nonprescription drugs included in the division's closed formulary and recommended by the division's adopted treatment guidelines may be prescribed and dispensed without preauthorization.

(2) Prescription and nonprescription drugs included in the division's closed formulary that exceed or are not addressed by the division's adopted treatment guidelines may be prescribed and dispensed without preauthorization.

(3) Drugs included in the closed formulary that are prescribed and dispensed without preauthorization are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier in accordance with subsection (g) of this section.

(e) Appeals process for drugs excluded from the closed formulary.

(1) For situations in which the prescribing doctor determines and documents that a drug excluded from the closed formulary is necessary to treat an injured employee's compensable injury and has prescribed the drug, the prescribing doctor, other requestor, or injured employee must request approval of the drug by requesting preauthorization, including reconsideration, in accordance with §134.600 of this title and applicable provisions of Chapter 19 of this title (relating to Agents' Licensing).

(2) If preauthorization is being requested by an injured employee or a requestor other than the prescribing doctor, and the injured employee or other requestor requests a statement of medical necessity, the prescribing doctor shall provide a statement of medical necessity to facilitate the preauthorization submission as set forth in §134.502 of this title (relating to Pharmaceutical Services).

(3) If preauthorization for a drug excluded from the closed formulary is denied, the requestor may submit a request for medical dispute resolution in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations).

(4) In the event of an unreasonable risk of a medical emergency, an interlocutory order may be obtained in accordance with §133.306 of this title (relating to Interlocutory Orders for Medical Benefits) or §134.550 of this title (relating to Medical Interlocutory Order).

(f) Initial pharmaceutical coverage.

(1) Drugs included in the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization and are not subject to retrospective review of medical necessity.

(2) Drugs excluded from the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization, except as referenced in subsection (b)(1)(C) of this section, and are subject to retrospective review of medical necessity.

(g) Retrospective review. Except as provided in subsection (f)(1) of this section, drugs that do not require preauthorization are subject to retrospective review for medical necessity in accordance with §133.230 of

this title (relating to Insurance Carrier Audit of a Medical Bill) and §133.240 of this title (relating to Medical Payments and Denials), and applicable provisions of Chapter 19 of this title.

- (1) Health care, including a prescription for a drug, provided in accordance with §137.100 of this title is presumed reasonable as specified in Labor Code §413.017, and is also presumed to be health care reasonably required as defined by Labor Code §401.011(22-a).
- (2) In order for an insurance carrier to deny payment subject to a retrospective review for pharmaceutical services that are recommended by the division's adopted treatment guidelines, §137.100 of this title, the denial must be supported by documentation of evidence-based medicine that outweighs the presumption of reasonableness established under Labor Code §413.017.
- (3) A prescribing doctor who prescribes pharmaceutical services that exceed, are not recommended, or are not addressed by §137.100 of this title, is required to provide documentation upon request in accordance with §134.500(13) of this title (relating to Definitions) and §134.502(e) and (f) of this title.

(h) This section will become effective for all drugs that are prescribed and dispensed for outpatient use on or after MM/DD/YY (intended to be a date certain approximately sixty days after the rule amendment is finally adopted).

§134.540. Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks.

(a) Applicability. The closed formulary applies to all drugs that are prescribed and dispensed for outpatient use for claims subject to a certified network on or after September 1, 2011 when the date of injury occurred on or after September 1, 2011.

(b) Preauthorization for claims subject to the Division's closed formulary. Preauthorization is only required for:

(1) drugs identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates;

(2) ~~any prescription drug created through compounding [any compound that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates]; and~~

(3) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined in Labor Code §413.014(a).

(c) Preauthorization of intrathecal drug delivery systems.

(1) An intrathecal drug delivery system requires preauthorization in accordance with the certified network's treatment guidelines and preauthorization requirements pursuant to Insurance Code Chapter 1305 and Chapter 10 of this title (relating to Workers' Compensation Health Care Networks).

(2) Refills of an intrathecal drug delivery system with drugs excluded from the closed formulary, which are billed using Healthcare Common Procedure Coding System (HCPCS) Level II J codes, and submitted on a CMS-1500 or UB-04 billing form, require preauthorization on an annual basis. Preauthorization for these refills is also required whenever:

(A) the medications, dosage or range of dosages, or the drug regime proposed by the prescribing doctor differs from the medications dosage or range of dosages, or drug regime previously preauthorized by that prescribing doctor; or

(B) there is a change prescribing doctor.

(d) Treatment guidelines. The prescribing of drugs shall be in accordance with the certified network's treatment guidelines and preauthorization requirements pursuant to Insurance Code Chapter 1305 and Chapter 10 of this title. Drugs included in the closed formulary that are prescribed and dispensed without preauthorization are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier in accordance with subsection (f) of this section.

(e) Appeals process for drugs excluded from the closed formulary.

(1) For situations in which the prescribing doctor determines and documents that a drug excluded from the closed formulary is necessary to treat an injured employee's compensable injury and has prescribed the drug, the prescribing doctor, other requestor, or injured employee must request

approval of the drug in a specific instance by requesting preauthorization in accordance with the certified network's preauthorization process established pursuant to Chapter 10, Subchapter F of this title (relating to Utilization Review and Retrospective Review) and applicable provisions of Chapter 19 of this title (relating to Agents' Licensing).

(2) If preauthorization is pursued by an injured employee or requestor other than the prescribing doctor, and the injured employee or other requestor requests a statement of medical necessity, the prescribing doctor shall provide a statement of medical necessity to facilitate the preauthorization submission as set forth in §134.502 of this title (relating to Pharmaceutical Services).

(3) If preauthorization for a drug excluded from the closed formulary is denied, the requestor may submit a request for medical dispute resolution in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations).

(4) In the event of an unreasonable risk of a medical emergency, an interlocutory order may be obtained in accordance with §133.306 of this title (relating to Interlocutory Orders for Medical Benefits) or §134.550 of this title (relating to Medical Interlocutory Order).

(f) Initial pharmaceutical coverage.

(1) Drugs included in the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization and are not subject to retrospective review of medical necessity.

(2) Drugs excluded from the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization and are subject to retrospective review of medical necessity.

(g) Retrospective review. Except as provided in subsection (f)(1) of this section, drugs that do not require preauthorization are subject to retrospective review for medical necessity in accordance with §133.230 of this title (relating to Insurance Carrier Audit of a Medical Bill), §133.240 of this title (relating to Medical Payments and Denials), the Insurance Code, Chapter 1305, applicable provisions of Chapters 10 and 19 of this title.

(1) In order for an insurance carrier to deny payment subject to a retrospective review for pharmaceutical services that fall within the treatment parameters of the certified network's treatment guidelines, the denial must be supported by documentation of evidence-based medicine that outweighs the evidence-basis of the certified network's treatment guidelines.

(2) A prescribing doctor who prescribes pharmaceutical services that exceed, are not recommended, or are not addressed by the certified network's treatment guidelines, is required to provide documentation upon request in accordance with §134.500(13) of this title (relating to Definitions) and §134.502(e) and(f) of this title.

(h) This section will become effective for all drugs that are prescribed and dispensed for outpatient use on or after MM/DD/YY (intended to be a date certain approximately sixty days after the rule amendment is finally adopted).