



TEXAS DEPARTMENT OF INSURANCE

Division of Workers' Compensation - Medical Fee Dispute Resolution (MS-48)

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MEDICAL FEE DISPUTE RESOLUTION FINDINGS AND DECISION

GENERAL INFORMATION

Requestor Name

American Specialty Pharmacy

Respondent Name

State Office of Risk Management

MFDR Tracking Number

M4-15-3615-01

Carrier's Austin Representative

Box Number 45

MFDR Date Received

July 3, 2015

REQUESTOR'S POSITION SUMMARY

Requestor's Position Summary: Review of submitted documentation does not find a position statement submitted by the requestor.

Amount in Dispute: \$1031.60

RESPONDENT'S POSITION SUMMARY

Respondent's Position Summary: "The Office was unable to locate preauthorization for the medication Thermacine, Laxacin and Promethazine as billed on this claim. Further research found that Thermacine and Promethazine is a status 'N' Medication in the ODG Treatment in Workers' Compensation (ODG)/Appendix A, ODG Workers' Compensation Drug Formulary. Furthermore, the Office is unable to locate Laxacin in the ODG drug formulary as it appears the ODG is silent regarding the use of this medication."

Response Submitted by: State Office of Risk Management

SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
September 8, 2014	Prescription Medication (Promethazine)	\$146.30	\$0.00
September 8, 2014	Over-the-Counter Medication (Laxacin)	\$186.60	\$0.00
September 8, 2014	Medical Food (Theramine)	\$698.70	\$0.00

FINDINGS AND DECISION

This medical fee dispute is decided pursuant to Texas Labor Code §413.031 and applicable rules of the Texas Department of Insurance, Division of Workers' Compensation.

Background

1. 28 Texas Administrative Code §133.307 sets out the procedures for resolving medical fee disputes.
2. 28 Texas Administrative Code §134.1 sets out the general medical reimbursement guidelines for non-network care.
3. 28 Texas Administrative Code §134.500 defines specific terms associated with pharmaceutical services.

4. 28 Texas Administrative Code §134.503 sets out the fee guidelines for pharmaceutical services.
5. 28 Texas Administrative Code §134.530 sets out the requirements for use of the closed formulary for claims not subject to certified networks.
6. The insurance carrier reduced payment for the disputed services with the following claim adjustment codes:
 - For Promethazine:
 - 197 – Payment denied/reduced for absence of precertification/authorization.
 - 4121 – Preauthorization is required for 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.
 - 193 – Original payment decision is being maintained. This claim was processed properly the first time.
 - For Laxacin:
 - 125 – Payment adjusted due to a submission/billing error(s).
 - 193 – Original payment decision is being maintained. This claim was processed properly the first time.
 - For Theramine:
 - 125 – Payment adjusted due to a submission/billing error(s).
 - 193 – Original payment decision is being maintained. This claim was processed properly the first time.

Issues

1. Is the insurance carrier’s denial of payment for Promethazine supported?
2. Is the insurance carrier’s denial of payment for Laxacin supported?
3. What is the applicable medical reimbursement standard for Laxacin?
4. Did the requestor support its request for reimbursement for Laxacin?
5. Are medical foods addressed in the division’s fee guidelines?
6. What is the applicable medical reimbursement standard for medical foods?
7. Did the requestor support its request for reimbursement for Theramine?

Findings

1. The insurance carrier denied reimbursement of Promethazine with claim adjustment reason codes 197 – “PAYMENT DENIED/REDUCED FOR ABSENCE OF PRECERTIFICATION/AUTHORIZATION,” and 4121 – “PREAUTHORIZATION IS REQUIRED FOR 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.” 28 Texas Administrative Code §134.530 (b) (1) states,

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 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).

The *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary* in effect on the date of service finds that Promethazine is an “N” status drug. Therefore, the medication requires preauthorization.

Review of the submitted information does not find that a request for preauthorization was requested or obtained in accordance with 28 Texas Administrative Code §134.600. For this reason, the insurance carrier’s denial reason is supported. Additional reimbursement for Promethazine cannot be recommended.

2. The insurance carrier denied reimbursement of Laxacin with claim adjustment reason code 125 – “PAYMENT ADJUSTED DUE TO A SUBMISSION/BILLING ERROR(S).” In their position statement, the insurance carrier stated, “...our cost containment vendor placed an incorrect CARC code on the explanation of benefits.”

Therefore, this denial was not maintained for MFDR. The insurance carrier further stated, "The Office was unable to locate preauthorization for the medication ... Laxacin ... as billed on this claim."

28 Texas Administrative Code §133.307(d)(2)(F) states, in relevant part, "The response shall address only those denial reasons presented to the requestor prior to the date the request for MFDR was filed with the division and the other party. Any new denial reasons or defenses raised shall not be considered in the review." The respondent's new denial reason shall therefore not be considered in this review.

3. Available information finds that Laxacin is a stimulant laxative using the ingredients docusate sodium and sennosides a and b. The FDA regulates medications with these ingredients under the over-the counter rules found in 21 CFR 310. Over-the-counter medications are subject to the fee guidelines found in 28 Texas Administrative Code §134.503(d), which states, "Reimbursement for nonprescription drugs or over-the-counter medications shall be the retail price of the lowest package quantity reasonably available that will fill the prescription."
4. Review of the submitted documentation finds that the requestor failed to support that the amount in dispute for Laxacin is the retail price of the lowest package quantity reasonably available, in accordance with 28 Texas Administrative Code §134.503(d). The requestor therefore failed to meet its burden to prove that the amount in dispute would satisfy the requirements of 28 Texas Administrative Code §134.1. For that reason, reimbursement for Laxacin cannot be recommended.
5. Submitted documentation contains some inconsistencies regarding the disputed service of Theramine. While the NDC number is not consistent, the majority of the documents used in the billing process indicate that the request involves Theramine, which is asserted by name.

In resolving disputes over the amount of payment due for services determined to be medically necessary and appropriate for treatment of a compensable injury, the role of the division's medical fee dispute resolution program is to adjudicate the payment given the relevant statutory provisions and rules. 28 Texas Administrative Code §134.1 titled *Medical Reimbursement* states in pertinent part that

- (e) Medical reimbursement for health care not provided through a workers' compensation health care network shall be made in accordance with:
 - (1) the Division's fee guidelines;
 - (2) a negotiated contract; or
 - (3) in the absence of an applicable fee guideline or a negotiated contract, a fair and reasonable reimbursement amount as specified in subsection (f) of this section.

Provision at Rule §134.1(e)(1) is first considered. The requestor billed the service in dispute using a DWC Form-066 Statement of Pharmacy Services. The rules and regulations for pharmacy services are found at Texas Administrative Code Title 28, Part 2, Chapter 134, Subchapter F, which include the fee guideline for pharmacy services found at §134.503. Available information about Theramine indicates that it is a medical food. For example, Theramine is found in the Pain Chapter of the Official Disability Guidelines under the procedure/topic "Medical Food."

To determine whether a fee guideline for medical foods is found in Subchapter F, the division examines the applicable portions of 28 Texas Administrative Code §134.503 amended to be effective October 23, 2011 (36 TexReg 6949), along with relevant definitions of terms pursuant to 28 Texas Administrative Code §134.500, adopted to be effective January 17, 2011 (35 TexReg 11344). Rule §134.503 states, in pertinent part:

- (a) Applicability of this section is as follows: (1) This section applies to the reimbursement of **prescription drugs and nonprescription drugs or over-the-counter medications** as those terms are defined in §134.500 of this title (relating to Definitions) for outpatient use in the Texas workers' compensation system

The definition of those terms under Rule §134.500 are as follows:

- (8) Nonprescription drug or over-the-counter medication--A non-narcotic **drug** [emphasis added] that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law.

- (12) Prescription **drug** [emphasis added] -- (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** [emphasis added] that under **federal law** [emphasis added] 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** [emphasis added] 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.

That is, only substances considered prescription drugs, nonprescription drugs, or over-the-counter drugs by federal law are addressed in the fee guideline Rule §134.503. Additionally, the definition of closed formulary at Rule §134.500(3) clarifies that substances approved by the Food and Drug Administration (FDA) as prescription and nonprescription drugs form the basis for the pharmacy closed formulary. The FDA is therefore the federal program that the division relies upon in order determine whether a medical food, such as Theramine, is categorized as a prescription drug, nonprescription drug, or an over-the-counter drug for the purposes of the formulary and for application of fees pursuant to Rule §134.503.

Information found on the FDA's website indicates that Medical foods are **not** regulated as drugs. Under the FDA's [Compliance Program Guidance Manual \(CPGM\)](#), medical foods are categorized under and regulated as "Food and Cosmetics." Specifically, under the Food Compliance Program numbered 7321.002 titled *Medical Foods – Import and Domestic*, implemented on August 24, 2006, the FDA states that "Only food regulations apply to medical foods." The division therefore concludes that the Theramine, a medical food and the service in dispute, is not addressed in Texas Administrative Code Title 28, Part 2, Chapter 134, Subchapter F because it is not regulated as a drug by the FDA. Consequently, a fee for the service in dispute cannot be established pursuant to 28 Texas Administrative Code §134.503.

Furthermore, review of the available documentation finds no service codes or assertions made by the requestor which point to other fee guidelines established under Texas Administrative Code Title 28, Part 2, under Chapter 134, nor does the division find evidence of a negotiated contract for the service in dispute. The division therefore concludes that §28 Texas Administrative Code 134.1(e)(3) applies to the Theramine in dispute.

6. Rule §134.1 requires that, in the absence of an applicable fee guideline or a negotiated contract, a fair and reasonable reimbursement amount as specified in subsection (f) shall apply. Pursuant to paragraph (f), in order to be considered fair and reasonable, a reimbursement amount shall:
- (1) be consistent with the criteria of Labor Code §413.011;
 - (2) ensure that similar procedures provided in similar circumstances receive similar reimbursement; and
 - (3) be based on nationally recognized published studies, published Division medical dispute decisions, and/or values assigned for services involving similar work and resource commitments, if available.
7. When filing for medical fee dispute resolution, a requestor is required by rule at 28 Texas Administrative Code §133.307(c)(2)(O) to provide "documentation that discusses, demonstrates, and justifies that the payment amount being sought is a fair and reasonable rate of reimbursement in accordance with §134.1 of this title (relating to Medical Reimbursement)..." Review of the submitted documentation finds that the requestor failed to articulate, discuss or explain why the amount in dispute for Theramine should be considered a fair and reasonable reimbursement amount for the disputed service. The requestor therefore failed to meet its burden to prove that the amount in dispute would satisfy the requirements of 28 Texas Administrative Code §134.1. For that reason, reimbursement for Theramine cannot be recommended.

Conclusion

The outcome of this medical fee dispute relied upon the evidence presented by the requestor and the respondent at the time of adjudication. Even though all the evidence was not discussed, it was considered. For the reasons stated above, the Division finds that the requestor has not established that reimbursement is due. As a result, the amount ordered is \$0.00.

ORDER

Based upon the documentation submitted by the parties and in accordance with the provisions of Texas Labor Code §413.031, the Division has determined that the requestor is entitled to \$0.00 reimbursement for the disputed services.

Authorized Signature

_____	<u>Laurie Garnes</u>	<u>December 17, 2015</u>
Signature	Medical Fee Dispute Resolution Officer	Date

YOUR RIGHT TO APPEAL

Either party to this medical fee dispute has a right to seek review of this decision in accordance with 28 Texas Administrative Code §133.307, 37 *Texas Register* 3833, applicable to disputes filed on or after June 1, 2012.

A party seeking review must submit a **Request to Schedule a Benefit Review Conference to Appeal a Medical Fee Dispute Decision** (form **DWC045M**) in accordance with the instructions on the form. The request must be received by the Division within **twenty** days of your receipt of this decision. The request may be faxed, mailed or personally delivered to the Division using the contact information listed on the form or to the field office handling the claim.

The party seeking review of the MFDR decision shall deliver a copy of the request to all other parties involved in the dispute at the same time the request is filed with the Division. **Please include a copy of the *Medical Fee Dispute Resolution Findings and Decision*** together with any other required information specified in 28 Texas Administrative Code §141.1(d).

Si prefiere hablar con una persona en español acerca de ésta correspondencia, favor de llamar a 512-804-4812.