



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

Texas Mutual Insurance Company

MFDR Tracking Number

M4-15-4146-01

Carrier's Austin Representative

Box Number 54

MFDR Date Received

August 24, 2015

REQUESTOR'S POSITION SUMMARY

Requestor's Position Summary: Submitted documentation does not include a position statement from the requestor. Accordingly, this decision is based on the information available at the time of review.

Amount in Dispute: \$130.40

RESPONDENT'S POSITION SUMMARY

Respondent's Position Summary: "The requestor billed for filling a prescription of Theramine to the claimant. ODG in its Pain chapter does not recommend the use of Theramine..."

Texas Mutual reviewed its claim file and found no documentation showing a medical emergency involving the drug above or that preauthorization was sought and obtained for it."

Response Submitted by: Texas Mutual Insurance Company

SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
June 17, 2015	Theramine	\$130.40	\$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

- 28 Texas Administrative Code §133.305 defines the terms used for medical disputes.
- 28 Texas Administrative Code §133.307 sets out the procedures for resolving medical fee disputes.
- 28 Texas Administrative Code §134.1 sets out the general medical reimbursement guidelines for non-network care.
- 28 Texas Administrative Code §134.500 defines specific terms associated with pharmaceutical services.
- 28 Texas Administrative Code §134.503 sets out the fee guidelines for pharmaceutical services.

6. Texas Insurance Code §1305.101 defines the duties of networks to provide medical treatment.
7. The insurance carrier reduced payment for the disputed services with the following claim adjustment codes:
 - CAC-45 – Charge exceeds fee schedule/maximum allowable or contracted/legislated fee arrangement.
 - 784 – Service exceeds recommendations of treatment guidelines (ODG)

Issues

1. Are medical foods addressed in the division’s pharmacy fee guidelines?
2. What is the applicable medical reimbursement standard for medical foods?
3. Did the requestor support its request for reimbursement?

Findings

1. 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, including fee guidelines for pharmacy services are found at §134.503. According to the medical bill, the disputed service is Theramine. Available information about Theramine indicates that it is a medical food. For example, Theramine is found in 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 applicability 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** [emphasis added] 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 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.

2. 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.
3. 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 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 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

Signature

Laurie Garnes
Medical Fee Dispute Resolution Officer

January 11, 2016
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.