



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

Memorial Compounding Pharmacy

Respondent Name

TASB RISK MGMT FUND

MFDR Tracking Number

M4-18-2903-01

Carrier's Austin Representative

Box Number 47

MFDR Date Received

April 16, 2018

REQUESTOR'S POSITION SUMMARY

Requestor's Position Summary: "Memorial Compounding Pharmacy has received several denials for bill with date of service (**11/15/2017**). The carrier denied the **original bill** as well, and the reconsideration based on **ABSENCE OF PRECERTIFICATION/AUTHORIZATION CLAIM.**"

Amount in Dispute: \$566.53

RESPONDENT'S POSITION SUMMARY

Respondent's Position Summary: "TASB-RMF considers any treatment that is not specifically cited, discussed, and approved in the current version of ODG, or is not FDA approved for the specific condition being treated, as being investigational or experimental"

Response Submitted by: TASB Risk Management Fund

SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
November 15, 2017	Pharmacy Services - Compounds	\$566.53	\$566.53

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 §133.240 sets out the general medical provisions for medical payments and denials.
- 28 Texas Administrative Code §133.307 sets out the procedures for resolving medical fee disputes.
- 28 Texas Administrative Code §134.502 sets out the procedures for pharmaceutical benefits.
- 28 Texas Administrative Code §134.503 sets out the fee guidelines for pharmaceutical services.
- 28 Texas Administrative Code §134.530 sets out the closed formulary requirements for claims not subject to

certified networks.

6. 28 Texas Administrative Code §19.2009 sets out the notice of determinations made in utilization review.
7. 28 Texas Administrative Code §19.2010 sets out the requirements prior to issuing adverse determination.
8. Texas Insurance Code, Chapter 4201 provides requirements related to utilization review.
9. The insurance carrier reduced payment for the disputed services with the following claim adjustment codes:
 - Payment adjusted for absence of precertification/authorization Claim/service denied because procedure/treatment is deemed experimental/investigational by the payer
 - Procedure/product not approved by the Food and Drug Administration Based on the findings of a review organization
 - Topical compound medications are not R&N per Peer Review. Applies to all lines
 - Additional payment made on appeal/reconsideration
 - Original payment decision is being maintained. Upon review, it was determined that this claim was processed properly
 - 1/25/18 – Rule 134.804 (a) services reviewed for reconsideration. Additional payment made or service adjustment amount may be zero
 - Exact duplicate claim/service Previously denied from eomb# 2939438 Applies to both lines
 - Per Rule 134.530 Pre-auth is required for any drug identified as investigational or experimental 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 pre-vailing standard of care as defined by labor code 413.014. The compound product is not used in approved FDA form & not approved by the FDA. Applies to both lines of the bill

Issues

1. Is TASB RISK MGMT FUND's reason for denial of payment supported?
2. Is Memorial Compounding Pharmacy (Memorial) entitled to reimbursement for the compound in question?

Findings

1. Memorial is seeking reimbursement for Meloxicam, Flurbiprofen, Tramadol HCL, Cyclobenzaprine HCL and Bupivacaine HCL dispensed on November 15, 2017.

TASB Risk Mgmt Fund denied the disputed drugs with reason codes "Payment adjusted for absence of precertification/authorization Claim/service denied because procedure/treatment is deemed experimental/investigational by the payer", "Procedure/product not approved by the Food and Drug Administration Based on the findings of a review organization", "Topical compound medications are not R&N per Peer Review. Applies to all lines", "Additional payment made on appeal/reconsideration", "Additional payment made on appeal/reconsideration", "Original payment decision is being maintained. Upon review, it was determined that this claim was processed properly", "1/25/18 – Rule 134.804 (a) services reviewed for reconsideration. Additional payment made or service adjustment amount may be zero", "Exact duplicate claim/service Previously denied from eomb# 2939438 Applies to both lines" and "Per Rule 134.530 Pre-auth is required for any drug identified as investigational or experimental 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 pre-vailing standard of care as defined by labor code 413.014. The compound product is not used in approved FDA form & not approved by the FDA. Applies to both lines of the bill"

28 Texas Administrative Code §133.305(b) requires that "If a dispute regarding...medical necessity exists for the same service for which there is a medical fee dispute, the disputes regarding...medical necessity shall be resolved prior to the submission of a medical fee dispute for the same services in accordance with Labor Code §413.031 and §408.021."

28 Texas Administrative Code §133.240(q) states that the insurance carrier is required to comply with 28 Texas Administrative Codes §19.2009 and 19.2010 when denying payment based on an adverse determination.

Review of the submitted documentation finds that TASB provided no evidence to support that TASB Risk Mgmt Fund performed a utilization review as required by 28 Texas Administrative Codes §134.240 and 19.2009.

28 Texas Administrative Code §134.530(b)(1) states that preauthorization is **only** required for:

- 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;
- 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
- 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).

Provision §134.530(b)(1)(A) preauthorization requirement is not discussed in this dispute because it was not asserted by either party in this dispute and is not applicable to the compound in question.

While not asserted by TASB Risk Mgmt Fund, Memorial was not required to seek preauthorization pursuant to §134.530(b)(1)(B) because none of the compounded ingredients have a status of "N" in the current edition of the ODG/Appendix A.

TASB, on behalf of TASB Risk Mgmt Fund, argued that “TASB-RMF considers any treatment that is not specifically cited, discussed, and approved in the current version of ODG, or is not FDA approved for the specific condition being treated, as being investigation or experimental.”

The determination of a service’s investigational or experimental nature is not subject to the *Official Disability Guidelines (ODG)*. Instead, it is determined on a case by case basis as a utilization review pursuant to Texas Insurance Code §4201.002. Further, Texas Insurance Code §4201.002(13) states that utilization review, in relevant part, “includes a system for prospective, concurrent, or retrospective review to determine the experimental or investigational nature of health care services.”

The division found **no evidence** that TASB engaged in a prospective or retrospective utilization review (UR) as required by Texas Insurance Code §4201.002 in order to establish that the following compound is investigational or experimental in nature:

Compound Cream in Dispute	
Ingredient	Amount
Meloxicam	0.18 gm
Flurbiprofen	4.8 gm
Tramadol HCl	6.0 gm
Cyclobenzaprine HCl	1.8 gm
Bupivacaine HCl	1.2 gm

Because TASSB Risk Mgmt Fund failed to perform UR on the above listed compound, the requirement for preauthorization under §134.530(b)(1)(C) **is not triggered** in this case. TASB Risk Mgmt Fund’s preauthorization denial is therefore not supported.

Absent any evidence that TASB Risk Mgmt Fund presented other defenses to Memorial before medical fee dispute resolution that conform with the requirements of Title 28, Part 2, Chapter 133, Subchapter C, the division finds that the compounds in question are eligible for reimbursement.

TASB Risk Mgmt Fund’s denial reason is therefore not sufficiently supported. The disputed compound will consequently be reviewed per applicable guidelines.

2. 28 Texas Administrative Code §134.503 applies to the compounds in dispute and states, in pertinent part:
 - (c) The insurance carrier shall reimburse the health care provider or pharmacy processing agent for prescription drugs the lesser of:

- (1) the fee established by the following formulas based on the average wholesale price (AWP) as reported by a nationally recognized pharmaceutical price guide or other publication of pharmaceutical pricing data in effect on the day the prescription drug is dispensed:
 - (A) Generic drugs: $((\text{AWP per unit}) \times (\text{number of units}) \times 1.25) + \4.00 dispensing fee per prescription = reimbursement amount;
 - (B) Brand name drugs: $((\text{AWP per unit}) \times (\text{number of units}) \times 1.09) + \4.00 dispensing fee per prescription = reimbursement amount;
 - (C) When compounding, a single compounding fee of \$15 per prescription shall be added to the calculated total for either paragraph (1)(A) or (B) of this subsection; or
- (2) notwithstanding §133.20(e)(1) of this title (relating to Medical Bill Submission by Health Care Provider), the amount billed to the insurance carrier by the:
 - (A) health care provider; or
 - (B) pharmacy processing agent only if the health care provider has not previously billed the insurance carrier for the prescription drug and the pharmacy processing agent is billing on behalf of the health care provider.

The compound in dispute was billed by listing each drug included in the compound and calculating the charge for each drug separately as required by 28 Texas Administrative Code §134.502(d)(2). Each ingredient is listed below with its corresponding reimbursement amount as applicable.

Drug	NDC	Generic(G) /Brand(B)	Price /Unit	Units Billed	AWP Formula	Billed Amt	Lesser of AWP and Billed
Meloxicam	38779274601	G	\$194.67	0.18	\$43.80	\$35.04	\$35.04
Flurbiprofen	38779036209	G	\$36.58	4.8	\$219.48	\$175.58	\$175.58
Tramadol HCL	38779237409	G	\$36.30	6	\$272.25	\$217.80	\$217.80
Cyclobenzaprine HCL	38779039509	G	\$46.33	1.8	\$104.25	\$83.39	\$83.39
Bupivacaine HCL	38779052405	G	\$45.60	1.2	\$68.40	\$54.72	\$54.72
						Total	\$566.53

The total reimbursement is therefore \$566.53. This amount is recommended.

Conclusion

The outcome of each independent medical fee dispute relies upon the relevant evidence presented by the requestor and the respondent at the time of adjudication. Though all the evidence in this dispute may not have been discussed, it was considered.

ORDER

Based on the submitted information, pursuant to Texas Labor Code Section 413.031 and 413.019 (if applicable), the division has determined the requestor is entitled to additional reimbursement for the disputed services. The division hereby ORDERS the respondent to remit to the requestor \$566.53, plus applicable accrued interest per 28 Texas Administrative Code §134.130, due within 30 days of receipt of this order.

Authorized Signature

Signature

Medical Fee Dispute Resolution Officer

Date

8/17/2018

YOUR RIGHT TO APPEAL

Either party to this medical fee dispute has a right to seek review of this decision in accordance with Rule §133.307, effective May 31, 2012, *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. **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.