TEXAS DEPARTMENT OF INSURANCE
Division of Workers' Compensation - Medical Fee Dispute Resolution (MS-48)
7551 Metro Center Drive, Suite 100, Austin, Texas 78744-1645
(512) 804-4000 | F: (512) 804-4811 | (800) 252-7031 | TDI.texas.gov | @TexasTDI

MEDICAL FEE DISPUTE RESOLUTION FINDINGS AND DECISION

GENERAL INFORMATION

Requestor Name
Memorial Compounding Pharmacy

Respondent Name
TASB Risk Mgmt Fund

MFDR Tracking Number
M4-19-0762-01

Carrier's Austin Representative
Box Number 47

MFDR Date Received
October 12, 2018

REQUESTOR'S POSITION SUMMARY

Requestor's Position Summary: "The above claimant received medication and the carrier still has not acknowledged receipt of service. The original bill was submitted to carrier on **03/05/2018** … The carrier denied the reconsideration based on lack of preauthorization or preauthorization was absent."

Amount in Dispute: $555.68

RESPONDENT'S POSITION SUMMARY

Respondent's Position Summary: "A peer review on file indicates that topical compounded medications are not supported by ODG and their use as a first line therapy is not recommended."

Response Submitted by: TASB Risk Mgmt Fund

SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
February 27, 2018	Pharmacy Services – Compound	$555.68	$555.68

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 §134.502 sets out the procedures for pharmaceutical benefits.
3. 28 Texas Administrative Code §134.503 sets out the fee guidelines for pharmaceutical services.
4. 28 Texas Administrative Code §134.530 sets out the closed formulary requirements for claims not subject to certified networks.
5. Texas Insurance Code, Chapter 4201 provides requirements related to utilization review.

6. The insurance carrier reduced payment for the disputed services with the following claim adjustment codes:
   - 55 – Claim/service denied because procedure/treatment is deemed experimental/investigational by the payer
   - 216 – Based on the findings of a review organization
   - 197 – Payment adjusted for absence of precertification/authorization
   - 114 – Procedure/product not approved by the Food and Drug Administration. 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 an approved FDA form & not approved by the FDA. Applies to both lines of the bill. Peer Reivew by Dr. Rey Ximenes, MD on file

Issues

1. Is the insurance carrier's reason for denial of payment supported?
2. Is Memorial Compounding Pharmacy (Memorial) entitled to reimbursement of the disputed services?

Findings

1. Memorial is seeking reimbursement of $555.68 for a compound dispensed on February 27, 2018. TASB Risk Mgmt Fund denied the disputed service with claim adjustment reason code 55 – "Claim/service denied because procedure/treatment is deemed experimental/investigational by the payer", 216 – "Based on the findings of a review organization", 197 – "Payment adjusted for absence of precertification/authorization", 197 – "Payment adjusted for absence of precertification/authorization" and 114 – "Procedure/product not approved by the Food and Drug Administration. 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 an approved FDA form & not approved by the FDA. Applies to both lines of the bill. Peer Reivew by Dr. Rey Ximenes, MD on file." 28 Texas Administrative Code §134.530(b)(1) states that 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).

   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 Risk Management Fund, argued that "A peer review on file indicates that topical compound medications are not supported by ODG and their use as first line therapy is not recommended."

   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 Risk Mgmt Fund 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
Baclofen	5.4 gm
Amantadine HCL	3.0 gm
Gabapentin USP	3.6 gm
Bupivacaine HCL	1.2 gm
Amitriptyline HCL	1.8 gm

Because TASB 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.

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 Risk Management Fund submitted a document dated March 21, 2018, as support for a utilization review of the disputed compound. The division concludes that the submitted documentation does not support that TASB Risk Mgmt Fund performed a utilization review as this document does not contain the elements of a utilization review required by 28 Texas Administrative Code §19.2009. or

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.

2. 28 Texas Administrative Code §134.503 applies to the services 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: ((AWP per unit) x (number of units) x 1.25) + $4.00 dispensing fee per prescription = reimbursement amount;
            (B) Brand name drugs: ((AWP per unit) x (number of units) x 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 compounds in dispute were 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). Reimbursement is calculated as follows:

Drug	NDC	Generic(G) /Brand(B)	Price /Unit	Units Billed	AWP Formula	Billed Amt	Lesser of AWP and Billed
Baclofen	38779038809	G	$35.63	5.4	$240.50	$190.78	$190.78
Amantadine HCL	38779041105	G	$24.23	3	$90.84	$72.69	$72.69
Gabapentin USP	38779246109	G	$59.85	3.6	$269.33	$204.66	$204.66
Bupivacaine HCL	38779052405	G	$45.60	1.2	$68.40	$54.72	$54.72
Amitriptyline HCL	38779018904	G	$18.24	1.8	$41.04	$32.83	$32.83
						Total	$555.68

The total allowable reimbursement for the compound in dispute is $555.68. This amount is recommended.

Conclusion

For the reasons stated above, the division finds that the requestor has established that additional reimbursement is due. As a result, the amount ordered is $555.68.

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 $555.68, 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	11/28/2018 Date

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.