

Maturus Software Technologies Corporation
DBA Matutech, Inc

881 Rock Street
New Braunfels, TX 78130
Phone: 800-929-9078
Fax: 800-570-9544

Notice of Independent Review Decision

September 15, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Compound cream to include baclofen 2%, diclofenac 10%, cyclobenzaprine 2%, Bupivacaine 1% and gabapentin 6%

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Diplomate, American Board of Physical Medicine and Rehabilitation and Pain Medicine

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who had an injury on xx/xx/xx, at work, when he slipped and fell and sustained injury to the upper back.

2013: On November 21, 2013, magnetic resonance imaging (MRI) of the thoracic spine was performed. The study was indicated due to upper back pain status-post fall. The findings revealed moderate anterior wedge compression fracture involving the T3 ventral body with approximately 50% anterior vertebral height loss. There was mild anterior wedge compression fracture involving the T2 vertebral body with less than 25% vertebral height loss. There was no evidence of osseous retropulsion, canal stenosis or cord myelomalacia. STIR images revealed edema signal along the superior endplate of the T2 vertebral body and superior half of the T3 vertebral body suggesting acute or subacute fractures.

On November 26, 2013, evaluated the patient for complaints of constant burning pain in the upper thoracic region between the scapulae. He also had occasional numbness and tingling in the left arm. The symptoms were aggravated by lifting overhead and standing. reviewed the MRI scan. The patient was utilizing ibuprofen and omeprazole. He had not participated in physical therapy (PT) nor had utilized a brace. The history was remarkable for arthritis, arthroscopy of the right shoulder, arthroscopy of the right knee and spinal fusion. X-rays of the thoracic spine showed mild wedging anteriorly of the T3 vertebral body and slight increase in the kyphosis of the thoracic area. diagnosed bilateral fractured thoracic vertebra and recommended a TLSO back brace. The patient was referred. The patient was kept on work restrictions. If the patient's symptoms did not improve, then an augmentation/kyphoplasty was to be considered.

On December 17, 2013, the patient stated he was wearing TLSO brace and noted increased pain with it, but after removing it the pain would decrease. He rated the pain at 6/10. Lumbar spine examination revealed Babinski sign downgoing bilaterally. The clonus was sustained on right. prescribed Ultram and Norco and recommended continuing TLSO brace. Therapy and rehabilitation was to be started.

2014: On January 13, 2014, the patient stated that he was wearing the TLSO brace at all times, but his pain level remained the same. The patient was currently working. X-rays of the thoracic spine showed further collapsed vertebral bodies. recommended weaning out of the brace. The patient was also allowed to work without brace. Work restrictions included no pushing, pulling, lifting, stopping or bending. The patient was recommended starting regular activities and referred for PT with modalities to include moist heat, ultrasound, electrical stimulation and myofascial release.

From January 15, 2014, through February 10, 2014, the patient underwent 10 sessions of PT with modalities to include therapeutic exercises, moist heat, therapeutic activities, postural stabilization training, resistive activities, manual therapy and home exercise program (HEP).

Per a prescription dated February 13, 2014, prescribed antiinflammatory cream to apply to the affected part 3-4 times daily.

On March 17, 2014, noted the patient had occasional burning thoracic pain. noted the patient had not started PT due to insurance not approving it. The patient reported 35% improvement with the compound cream. Lumbar examination revealed increased kyphosis and muscle spasm. diagnosed empty fractured thoracic vertebrae and empty sprain thoracic region. Since the PT was denied by the insurance, recommended HEP and a compound cream to include baclofen 2%, diclofenac 10%, cyclobenzaprine 2%, Bupivacaine 1% and gabapentin 6%. The patient was to apply 1-2 g of the cream to the affected area 3-4 times per day. He was to continue work without restrictions.

On June 5, 2014, peer review. The following additional records were documented: *"The patient was seen in the emergency room (ER) on xx/xx/xx, with complaints of thoracic back pain. He denied head trauma or loss of consciousness (LOC). Examination revealed mid-thoracic back pain and normal reflexes. The diagnosis was cervical sprain, thoracic sprain and lumbar sprain. X-rays of the cervical spine showed bones appeared de-mineralized, C7 well seen on lateral Swimmer's view of thoracic series and was unremarkable. Thoracic x-ray showed bones de-mineralized, slightly prominent curvature of the cervicothoracic junction with no acute fracture seen. X-rays of the lumbar spine showed moderate disc space narrowing at L5-S1. The patient was seen on October 18, 2013, for 4/10 back pain. The examination revealed mild tenderness in the upper thoracic to lower lumbar area, otherwise unremarkable. The patient was prescribed Mobic and Norco and recommended returning to work (RTW) on light duty. The October 24, 2013, follow up note identified the patient was ready to be released today. His pain was 1-2/10. Per a DWC 69 Form dated October 24, 2013, the patient was assigned maximum medical improvement (MMI) with no permanent impairment. On November 16, 2013, the patient was seen for continued pain in the same area. The patient complained of numbness with lifting arm. Examination revealed mild tenderness only. The patient was recommended RTW full duty. There were PT notes beginning January 30, 2014, through February 17, 2014. The February 13, 2013, follow up report noted the patient had good results with increased endurance and decreased pain, was taking pain medications only as needed, had been working and was able to function at work with no problems. Continued PT and a compounded cream ordered to be applied three to four times per day. saw the patient on April 21, 2014, who reported pain at 5/10, constant ache with sharp pain, ortho released a month ago. Examination revealed mild tenderness. The patient was recommended impairment rating (IR). saw the claimant and assigned MMI as of April 21, 2014, with a 15% WPI."* noted that there were no pharmacy notes, though the February 13, 2014, office visit note prescribed a compound topical cream. The ODG did not support a topical compounded cream and would be abruptly discontinued.

Per a utilization review dated July 15, 2014, the request for compound cream to include baclofen 2%, diclofenac 10%, cyclobenzaprine 2%, Bupivacaine 1% and gabapentin 6% was denied with the following rationale: *"Regarding a compound cream to include baclofen 2%, diclofenac 10%, cyclobenzaprine 2%, Bupivacaine 1% and gabapentin 6%, ODG-TWC states that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no evidence for use of any other anti-epilepsy drug and muscle relaxants as a topical product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, on March 17, 2014, the patient claimant has history of pain in the thoracic region. The claimant has noticed a 35 percent improvement where using a compound cream. However, there is no thorough documentation and examination of current pain complaints. Most recent record submitted is more than 60 days ago. Further, there is no evidence of measurable objective functional improvement. There is no documentation that current medications regimen is insufficient to alleviate pain symptoms. There is no*

evidence of failed trials of antidepressants and anticonvulsants. Considering all these factors, recommend non-certification.”

Per a reconsideration review dated August 21, 2014, the appeal for compound cream to include baclofen 2%, diclofenac 10%, cyclobenzaprine 2%, Bupivacaine 1% and gabapentin 6% was denied with the following rationale: *“Per the record review, there is no specific area of tenderness or pain and no discussion of localized pain but just the general diagnosis of thoracic pain and muscle spasm. There is no information about the treatment or examination history. Per the guidelines, topical analgesics recommended as an option as indicated. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Therefore, the request is not certified.”*

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The physical findings and diagnosis do not support the use of multiple medications in topical form, and this specific medication was demonstrated to have low efficacy during the patient’s care. Thus the medication is not approved within the guidelines.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES