

Case Number:	CM15-0128402		
Date Assigned:	07/14/2015	Date of Injury:	04/07/2013
Decision Date:	08/18/2015	UR Denial Date:	06/04/2015
Priority:	Standard	Application Received:	07/02/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 56 year old male, who sustained an industrial injury on 4/07/2013. He reported a slip and fall landing on his back. Diagnoses include lumbar strain, herniated nucleus pulposus, radiculopathy, anxiety disorder and mood disorder. Treatments to date include activity modification, narcotic, topical cream, muscle relaxant, and physical therapy. Currently, he complained of burning low back pain with radiation down left lower extremities associated with numbness and tingling in bilateral lower extremities. Pain was rated 9/10 VAS. On 5/23/15, the physical examination documented tenderness to lumbar spine and left sciatic notch, decreased lumbar range of motion and decreased sensation in lower extremities. The plan of care included prescriptions for a topical compound cream (Flurbiprofen 15%/ Cyclobenzaprine 10%/ Baclofen 2%/ Lidocaine 5%; 150 grams); Tramadol 50mg tablets, one twice a day #60; Gabapentin 300mg tablets #100; and Tizanidine 4mg, one tablet twice a day #60.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Flurbiprofen 15% Cyclobenzaprine 10% Baclofen 2% Lidocaine 5% 150gms: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 111-113.

Decision rationale: The MTUS Guidelines recommend the use of topical analgesics as an option for the treatment of chronic pain, however, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Topical NSAIDs, have been shown to be superior to placebo for 4-12 weeks for osteoarthritis of the knee. The injured worker's pain is not described as pain from osteoarthritis. Topical flurbiprofen is not an FDA approved formulation. The MTUS Guidelines state that there is no evidence for use of muscle relaxants, such as cyclobenzaprine, as a topical product. Non-sedating muscle relaxants (for pain) are recommended by the MTUS Guidelines with caution for short periods for treatment of acute exacerbations of chronic low back pain, but not for chronic or extended use. In most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Baclofen is among the muscle relaxant medications with the most limited published evidence in terms of clinical effectiveness. Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation are commonly reported side effects with the use of Baclofen. Baclofen is recommended for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Topical lidocaine is used primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. There is no clear evidence in the clinical reports that this injured worker has neuropathic pain that has failed treatment with trials of anti-depressants and anti-convulsants. As at least one of the medications in the requested combination medication is not recommended by the guidelines, the request for Flurbiprofen 15% Cyclobenzaprine 10% Baclofen 2% Lidocaine 5% 150gms is determined to not be medically necessary.

Tramadol 50mg BID #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Section, Weaning of Medications Section Page(s): 74-95, 124.

Decision rationale: Tramadol is a central acting synthetic opioid that exhibits opioid activity with a mechanism of action that inhibits the reuptake of serotonin and norepinephrine with side effects similar to traditional opioids. The MTUS Guidelines do not recommend the use of opioid pain medications, in general, for the management of chronic pain. There is guidance for the rare instance where opioids are needed in maintenance therapy, but the emphasis should remain on non-opioid pain medications and active therapy. Long-term use may be appropriate if the patient is showing measurable functional improvement and reduction in pain in the absence of non-compliance. Functional improvement is defined by either significant improvement in activities of

daily living or a reduction in work restriction as measured during the history and physical exam. In this case, there is no documentation of significant pain relief or increase in function with the use of Tramadol. It is not recommended to discontinue opioid treatment abruptly, as weaning of medications is necessary to avoid withdraw symptoms when opioids have been used chronically. This request however is not for a weaning treatment, but to continue treatment. The request for Tramadol 50mg BID #60 is determined to not be medically necessary.

Gabapentin 300mg at bedtime #100: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs (AEDs) Section Page(s): 16-21.

Decision rationale: The MTUS Guidelines recommend the use of anti-epilepsy drugs for neuropathic pain. Most randomized controlled trials for the use of anti-epilepsy drugs for neuropathic pain have been directed at post-herpetic neuralgia and painful polyneuropathy, with polyneuropathy being the most common example. There are few RCTs directed at central pain, and none for painful radiculopathy. A good response to the use of anti-epilepsy drugs has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response to this magnitude may be the trigger for switching to a different first line agent, or combination therapy if treatment with a single drug fails. After initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of anti-epilepsy drugs depends on improved outcomes versus tolerability of adverse effects. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and post-herpetic neuralgia and has been considered as a first line treatment for neuropathic pain. There is no documentation of significant pain relief or improvement in function with the use of gabapentin. The request for Gabapentin 300mg at bedtime #100 is determined to not be medically necessary.

Tizanidine 4mg BID #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Section, Weaning of Medications Section Page(s): 63, 66, 124.

Decision rationale: Non-sedating muscle relaxants (for pain) are recommended by the MTUS Guidelines with caution for short periods for treatment of acute exacerbation of chronic low back pain, but not for chronic or extended use. Drowsiness, dizziness and lightheadedness are commonly reported adverse reactions with the use of Robaxin. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility, but in most low back pain cases there is no benefit beyond NSAIDs. Efficacy appears to diminish over time and prolonged

use may lead to dependence. The injured worker is being treated for chronic pain. There is no evidence of an acute exacerbation of pain. Discontinuation of chronically used muscle relaxants should include a tapering dose to decrease withdrawal symptoms. This request however is not for a tapering dose. The request for Tizanidine 4mg BID #60 is determined to not be medically necessary.