

Case Number:	CM15-0115867		
Date Assigned:	06/24/2015	Date of Injury:	07/17/2013
Decision Date:	08/24/2015	UR Denial Date:	06/11/2015
Priority:	Standard	Application Received:	06/16/2015

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: Arizona, Michigan

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 52 year old male who sustained an industrial injury on 07/17/2013 resulting in pain/injury to the low back. The injured worker was diagnosed with low back strain. Treatment provided to date has included: lumbar spine surgery; physical therapy (9); epidural steroid injections (2014) resulting in temporary but good relief; radiofrequency facet rhizotomy and ablation (2014) resulting in 75% overall improvement in symptoms; medications (Motrin, Relafen, Prilosec, and Mobic) without significant relief, and conservative therapies/care. Diagnostic tests performed include: x-rays of the lumbar spine (2013) showing abnormal findings with no fractures; and MRI of the lumbar spine (2014) showing mild to moderate multilevel degenerative disc disease and facet arthropathy with central canal and neuroforaminal narrowing, and multilevel disc protrusions. Other noted dates of injury documented in the medical record include: 2012 and 2014. Although there were no noted comorbidities, there was a history of acid reflux. On 04/08/2015, physician progress report noted complaints of residual burning low back pain. The pain was rated 5-6/10 in severity, and was described as frequent to constant, moderate to severe, and associated with numbness and tingling in the lower extremities bilaterally. The pain was noted to be aggravated by prolonged standing, sitting, walking, bending, arising from the sitting position, ascending or descending stairs, stooping, and activities of daily living. His symptoms were temporarily relieved with medications and activities restrictions. There were no additional complaints, and no reports of gastrointestinal issues. Prior to this exam, the injured worker was seen on 01/17/2015 and was noted to have lumbar pain with a pain level of 7/10. At this time, the injured worker was prescribed Synapryn, tabradol,

Deprizine, Dicopanol, Fanatrex, topical Ketoprofen cream, and topical cyclobenzaprine. Current medications , as of 04/08/2015, include Synapryn, tabradol, Deprizine, Dicopanol, Fanatrex, topical capsaicin, flurbiprofen, topical menthol, gabapentin, and Cyclobenzaprine. The physical exam revealed tenderness to palpation (TTP) at the lumbar paraspinal musculature over the lumbosacral junction, restricted lumbar range of motion, decreased sensation to pin-prick and light touch in the bilateral lower extremities, and mildly decreased muscle strength in the lower extremities. The provider noted diagnoses of status post lumbar spine surgery with residual pain, rule out lumbar disc displacement, and rule out lumbar radiculopathy. Plan of care includes continued current medications, shockwave therapy for the lumbar spine, and follow-up. The injured worker's work status remained temporarily totally disabled. The request for authorization and IMR (independent medical review) includes: Synapryn 10mg/1ml 500ml (5ml), tabradol 250ml, Deprizine 15mg/ml 250ml, Dicopanol 5mg/ml 150ml, Fanatrex 25mg 420ml 5ml, Ketoprofen 20% 167gm, and Cyclobenzaprine 110gm.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/1ml 500ml (5ml): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate), and Opioids Page(s): 50, 74-96.

Decision rationale: Synapryn is a compounded medication that contains Tramadol (opioid) and glucosamine. MTUS discourages long-term usage of opioids unless there is evidence of "ongoing review and documentation of pain relief, improvement in functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The MTUS recommends Glucosamine for the treatment of moderate arthritis pain (particularly in the knee). The treating physician does not document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; or 5) improvement in function. There is also no diagnosis of arthritis, and no clinical reason for oral suspension provided in the clinical notes. These are necessary to meet MTUS guidelines. As such, the request for Synapryn 10mg/1ml oral suspension 500ml is not medically necessary.

Tabradol 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) and Muscle relaxants (for pain) Page(s): 41-42, 63-64.

Decision rationale: Tabradol (brand names: Amrix, Flexeril and Fexmid) is a centrally acting skeletal muscle relaxant. The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Cyclobenzaprine (Amrix, Flexeril, Fexmid and other generic forms) is recommended for a short course of treatment (with greatest effect within the first 4 days) and not recommended for long term use. The clinical notes show that the injured worker has been prescribed Tabradol since 01/07/2015 with little to no evidence of muscle spasms, diagnoses involving musculature, reduction in pain or improvement in function in relation to the use of this medication. There is an additional request for Cyclobenzaprine in the topical form. In addition, the MTUS does not recommend or support the long-term use of muscle relaxants. Therefore, Tabradol 250ml is not medically necessary.

Deprizine 15mg/ml 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

Decision rationale: Deprizine (Zantac or ranitidine) is an oral stomach acid reducer medication. Although, the MTUS and ODG are silent in the recommendation of this medication, the MTUS does recommends gastro protective medications for injured workers with a high risk of gastrointestinal (GI) events, upper GI disease or medication induced gastritis. Although the injured worker had a previous history of heartburn/acid reflux due to long-term use of Motrin, there had not been any recent reports of GI issues since 05/2013. In addition, there is no clinical reason for oral suspension provided in the clinical notes, neither is there any indication that she has trialed and failed other recommended first line PPI's as supported by the guidelines. As such, Deprizine 15mg/ml 250ml is not medically necessary.

Dicopanol 5mg/ml 150ml: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) / Insomnia, Insomnia treatment.

Decision rationale: The MTUS did not specifically address the treatment of insomnia in chronic pain therefore other guidelines were consulted. Per the ODG, correcting sleep deficits is recommended as non-restorative sleep is one of the strongest predictors of pain. Sedating antihistamines have been suggested for sleep aids, for example, Diphenhydramine, tolerance develops within a few days and next day sedation, impaired psychomotor and cognitive function have been noted. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. Dicopanol is Diphenhydramine and a review of the injured workers medical records did not reveal any difficulty swallowing or tolerating non-liquid oral medications without this information the request for Dicopanol 5mg/ml oral suspension 150ml is not medically necessary.

Fanatrex 25mg 420ml 5ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin) Page(s): 49. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back & Lumbar & Thoracic (Acute & Chronic) Chapter, Gabapentin (Neurontin); and Pain Chapter, Gabapentin (Neurontin).

Decision rationale: Per the MTUS, Fanatrex (gabapentin) is a compounded form of an anti-epilepsy drug (AEDs - also referred to as anti-convulsants). These drugs have 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. The ODG states that compounded drugs are not recommended as first-line therapy. FDA-approved drugs should be given adequate trial, if these are inadequate, ineffective or contraindicated in the individual patient, then compounded drugs with FDA-approved ingredients can be considered. The clinical documentation submitted for review does not indicate diagnoses of diabetic neuropathy or postherpetic neuralgia. Painful neuropathic symptoms were noted; however, there is no indication for the compounded oral suspension form of this drug in such a low dose (non-therapeutic dose) in comparison to the recommended dose of oral gabapentin in tablet form. In addition, there is no documented failed trial of the FDA-approved form of this drug, and no indication as to the reason that the FDA- approved form is contraindicated in the injured worker. As such, the request for Fanatrex (gabapentin) 25mg/ml 420ml is not medically necessary.

Ketoprofen 20% 167gm: Upheld

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

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

Decision rationale: According to the MTUS, Topical Analgesic are recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to

determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis and absorption of the drug depends on the base it is delivered in. In this case, Ketoprofen is not FDA approved for topical application as outlined in the MTUS guidelines. As a result, the topical application of Ketoprofen 20% 167gm is not medically necessary.

Cyclobenzaprine 110gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril); Muscle relaxants (for pain); and Topical Analgesics Page(s): 41-42, 63-64, 111-113.

Decision rationale: Cyclobenzaprine (brand names: Amrix, Flexeril and Fexmid; generic form: Tabradol) is a centrally acting skeletal muscle relaxant. The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Cyclobenzaprine (Amrix, Flexeril, Fexmid and other generic forms) is recommended for a short course of treatment (with greatest effect within the first 4 days) and not recommended for long term use. According to the MTUS guidelines: Topical Analgesic are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Cyclobenzaprine (a muscle relaxant) is not recommended for use as a topical agent. The clinical notes show that the injured worker has been prescribed Cyclobenzaprine since 01/07/2015 with little to no evidence of muscle spasms, diagnoses involving musculature, reduction in pain or improvement in function in relation to the use of this medication. Also, there is an additional request for Cyclobenzaprine in oral form. In addition, the MTUS does not recommend or support the long-term use of muscle relaxants, multiple or duplicate forms of a muscle relaxants, or medications/agents that are not recommended for topical application. Therefore, Cyclobenzaprine 110gm is not medically necessary.