

Case Number:	CM14-0138279		
Date Assigned:	10/08/2014	Date of Injury:	12/05/2013
Decision Date:	11/07/2014	UR Denial Date:	08/20/2014
Priority:	Standard	Application Received:	08/26/2014

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. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation and is licensed to practice in Illinois. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 reported an injury on 12/05/2013 due to the repetitive and continual nature of his daily work tasks. Diagnoses were headache, ocular pain bilateral, unspecified respiratory disorder, bilateral shoulder sprain/strain, rule out joint derangement, bilateral elbows sprain/strain, rule out joint derangement, rule out bilateral carpal tunnel syndrome, lumbar spine sprain/strain, rule out disc displacement, radiculopathy lumbar region, mood disorder, anxiety disorder, and sleep disorder. Physical examination dated 09/11/2014 revealed complaints of headaches and eye pain. There were complaints of difficulty breathing, complaints of burning bilateral shoulder pain that radiated down the arms to the fingers, associated with muscle spasms. The patient rated his pain an 8/10 on the right and 9/10 on the left. There were complaints of burning bilateral elbow pain and muscle spasms. The pain was described as constant, moderate to severe. The pain was rated an 8/10 on the right and 7/10 on the left. There were complaints of burning bilateral wrist pain and muscle spasms. The pain was described as constant, moderate to severe. The pain was rated a 7/10 on the right, and 8/10 on the left. The patient had complaints of burning, radicular low back pain and muscle spasms. The injured worker rated the pain as an 8/10. The patient was described as constant, moderate to severe. It was reported that the injured worker was frustrated by his injury, and was experiencing stress, anxiety, insomnia, and depression. The injured worker reported that the medications do offer temporary relief of the pain and improve his ability to have restful sleep. The injured worker denied any problems with the medications. Neurological examination of bilateral lower extremities revealed slightly decreased sensation to pin prick and light touch at the L5 and S1 dermatomes bilaterally. Motor strength was 4/5 in all the represented muscle groups in the bilateral lower extremities. Deep tendon reflexes were 2+ and symmetrical in the bilateral lower

extremities. Medications were Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, a compounded topical ointment. The Request for Authorization was submitted.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Ketoprofen 20% cream #165g: Upheld

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

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

Decision rationale: The decision for compounded Ketoprofen 20% cream quantity 165g is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are experimental in use, with few randomized controlled trials to determine efficacy or safety, and primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. Ketoprofen is not currently FDA approved for a topical application. The medical guidelines do not support the use of compounded topical analgesics. There was no significant functional benefit reported from the use of this medication. Furthermore, the request does not indicate a frequency for the medication. There were no other significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Compounded Cyclobenzaprine 5% cream 100g: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics and Cyclobenzaprine Page(s): 111 and 41.

Decision rationale: The decision for compounded Cyclobenzaprine 5% cream 100g is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicates that topical analgesics are experimental in use, with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxant, as there is no evidence for use of any other muscle relaxant as a topical product. The medical guidelines do not support the use of compounded topical analgesics. The guidelines do not recommend the topical use of Cyclobenzaprine. Furthermore, the request does not indicate a frequency for the medication. There were no other significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Synapryn 10mg/ml #500ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ongoing Management Page(s): 78. Decision based on Non-MTUS Citation <http://www.drugs.com/cons/fusepaq-synapryn.html>

Decision rationale: The decision for compounded Cyclobenzaprine 5% cream 100g is not medically necessary. The California Medical Treatment Utilization Schedule Guidelines indicates that topical analgesics are experimental in use, with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxant, as there is no evidence for use of any other muscle relaxant as a topical product. The medical guidelines do not support the use of compounded topical analgesics. The guidelines do not recommend the topical use of Cyclobenzaprine. Furthermore, the request does not indicate a frequency for the medication. There were no other significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Tabradol 1mg/ml #250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 64. Decision based on Non-MTUS Citation <http://www.drugs.com/cons/fusepaq-tabradol.html>

Decision rationale: The decision for Tabradol 1 mg/mL quantity 250 mL is not medically necessary. The California Medical Treatment Utilization Schedule, ACOEM, and Official Disability Guidelines do not directly address Tabradol suspension medication. According to Drugs.com, this medication contains Cyclobenzaprine which is a muscle relaxant. The California MTUS does address Cyclobenzaprine. The medical guidelines state that Cyclobenzaprine (Flexeril) is recommended for a short course of therapy. Flexeril is more effective than placebo in the management of back pain; however, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first four days of treatment, suggesting that shorter courses may be better. This medication is not recommended to be used for longer than 2 to 3 weeks. There was a lack of documentation detailing a clear indication for the use of Tabradol oral suspension. It was not reported why the injured worker could not take a pill form of Cyclobenzaprine. Also, the clinical documentation submitted for review does provide evidence that the injured worker has been on this medication for an extended duration of time. The medical guidelines recommend no longer than 2 to 3 weeks usage of this medication.

Furthermore, the request does not indicate a frequency for the medication. There were no other significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Deprizine 15mg/ml #250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/deprizine.html>

Decision rationale: The decision for Deprizine 15 mg/mL quantity 250 mL is not medically necessary. The California Medical Treatment Utilization Schedule, ACOEM, and Official Disability Guidelines do not directly address Deprizine 15 mg/mL suspension medication. According to Drugs.com, this medication contains Ranitidine which is used for acid reflux. The California Medical Treatment Utilization Schedule does address proton pump inhibitors and H2 receptor antagonists. Ranitidine is an H2 receptor antagonist. According to the medical guidelines, clinicians should determine if the patient is at risk for gastrointestinal events which include age greater than 65 years, a history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or on an anticoagulant or using high dose/multiple NSAIDs. For patients with no risk factor and no cardiovascular disease, a nonselective NSAID is okay (e.g. Ibuprofen, Naproxen, etcetera). Patients at intermediate risk for gastrointestinal events and no cardiovascular disease (1) a nonselective NSAID with neither a PPI (proton pump inhibitor), for example 20 mg Omeprazole daily or Misoprostol (200 ug 4 times daily), or (2) a Cox 2 selective agent. Long term PPI use (greater than 1 year) has been shown to increase the risk of hip fracture. For patients at high risk for gastrointestinal events with no cardiovascular disease, a Cox 2 selective agent plus a PPI should be recommended if absolutely necessary. For treatment of dyspepsia secondary to NSAID therapy, it is recommended to stop the NSAID, switch to a different NSAID, or consider H2 receptor antagonist or a PPI. It was not reported that the injured worker was having any type of gastrointestinal events nor was there a diagnosis to support the use of the requested medication. The request does not indicate a frequency for the medication. It was not reported why the injured worker was taking a suspension medication instead of an oral tablet form medication. The clinical information submitted for review does not provide evidence to justify continued use. Therefore, this request is not medically necessary.

Dicopanol 5mg/ml 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/dicopanol.html> Pain, Insomnia Treatment

Decision rationale: The decision for Dicopanol 5 mg/mL 150 mL is not medically necessary. The California Medical Treatment Utilization Schedule, ACOEM, and Official Disability Guidelines do not directly address this medication. According to Drugs.com, this medication contains Diphenhydramine Hydrochloride (Benadryl). Benadryl is an over the counter medication that is sometimes used for insomnia treatment. According to the Official Disability Guidelines, insomnia treatment can be used with over the counter medications such as antihistamines that have been suggested for sleep aids (for example, Diphenhydramine). Tolerance seems to develop within a few days. Next day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess, and tiredness. This medication can be purchased over the counter. It was not reported why the injured worker was taking an oral suspension medication instead of a pill form medication. There was a lack of documentation detailing a clear indication for the use of an oral suspension medication. The request does not indicate a frequency for the medication. Continued use of this medication would not be supported. The clinical information submitted for review does not provide evidence to justify continued use. Therefore, this request is not medically necessary.

Fanatrex 25mg/ml 420ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs Page(s): 16-22. Decision based on Non-MTUS Citation Drugs.com: <http://www.drugs.com/pro/fanatrex.html>

Decision rationale: The decision for Fanatrex 25 mg/mL 420 mL is not medically necessary. The California Medical Treatment Utilization Schedule, ACOEM, and Official Disability Guidelines do not address this medication directly. According to Drugs.com, this medication contains Neurontin (Gabapentin). According to the California Medical Treatment Utilization Schedule Guidelines, Gabapentin has been shown to be effective for diabetic painful neuropathic and post-herpetic neuralgia and has been considered a first line treatment of neuropathic pain. 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 AEDs depends on improved outcomes versus tolerability of adverse effects. The medical documents did not indicate that the injured worker had significant difficulties taking traditional tablet medications, which would indicate the injured worker's need for oral suspension medications. The provider's request does not indicate the frequency of the medications. Therefore, this request is not medically necessary.

Unknown physical therapy sessions: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine.

Decision rationale: The decision for unknown physical therapy sessions is not medically necessary. The California Medical Treatment Utilization Schedule states that physical medicine with passive therapy can provide short term relief during the early phases of pain treatment, and are directed at controlling symptoms such as pain, inflammation, and swelling, and to improve the rate of healing soft tissue injuries. Treatment is recommended with a maximum of 9 to 10 visits for myalgia and myositis and 8 to 10 visits may be warranted for treatment of neuralgia, neuritis, and radiculitis. Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices. The functional benefit from previous physical therapy was not reported. The request submitted does not indicate how many visits of physical therapy sessions are being requested. The injured worker is expected to have transitioned to a home exercise program. Reasons why a home exercise program could not be continued for further gains were not reported. The clinical information submitted for review does not provide evidence to justify unknown physical therapy sessions. Therefore, this request is not medically necessary.

Platelet rich plasma (PRP) treatment: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Shoulder (Acute & Chronic)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Platelet Rich Plasma

Decision rationale: The decision for PRP treatment is not medically necessary. The Official Disability Guidelines state that platelet rich plasma is not recommended except in a research setting. Platelet rich plasma therapies are more complicated than previously acknowledged, and an understanding of the fundamental processes and pivotal molecules involved will need to be elucidated. PRP therapies in clinical trials await assessment. PRP injections to the ankle are not recommended, with recent higher quality evidence showing this treatment to be no better than placebo. Platelet rich plasma injections for the elbow are still under study. As platelet rich plasma is not recommended in the guidelines, the injections would not be indicated. There were no other significant factors provided to justify the use outside of current guidelines. Also, the request does not indicate where the platelet rich plasma injection was to be given. Therefore, this request is not medically necessary.

Unknown prescription of Terocin patches: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Capsaicin, Salicylates Topical, Topical Analgesic, and Lidocaine Page(s): 28, 105, 111.
Decision based on Non-MTUS Citation Drugs.com

Decision rationale: The decision for unknown prescription of Terocin patches is not medically necessary. According to Drugs.com, Terocin is a topical analgesic containing Capsaicin, Lidocaine, Menthol and Methyl Salicylate. The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first line treatment (tricyclic or SNRI) antidepressant or an AED such as Gabapentin or Lyrica). No other commercially approved topical formulation of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. The medical guidelines do not support the use of compounded analgesics. The request submitted does not indicate a frequency or a quantity for the medication. The request does not indicate where this medication is to be applied. There were no other significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.