

Case Number:	CM14-0029424		
Date Assigned:	06/20/2014	Date of Injury:	09/14/2013
Decision Date:	07/24/2014	UR Denial Date:	02/10/2014
Priority:	Standard	Application Received:	03/07/2014

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 Anesthesia, has a subspecialty in Acupuncture & Pain Medicine and is licensed to practice in California. 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:

A 34 year old male injured worker with date of injury 9/14/13 with related low back pain. Per progress report dated 4/8/14, he complained of sharp, stabbing radicular low back pain with muscle spasms, rated 8/10 constant. He also complained of sharp, stabbing tail bone pain rated 6-7/10, frequent to constant. The injured worker stated that the symptoms persisted but the medications did offer him temporary relief of pain and improved his ability to have restful sleep. He denied any problems with the medications. The pain was also alleviated by activity restrictions. Per examination, he was able to heel-toe walk; however he had pain with heel walking. He was able to squat to approximately 7% of normal due to the pain in the low back. There was tenderness to palpation at the lumbar paraspinal muscles. Decreased Rom, straight leg raise was positive bilaterally, Kemp's test was positive bilaterally. MRI of the lumbar spine dated 5/12/14 revealed early disc desiccation at L5-S1 level; diffuse disc protrusion with effacement of the thecal sac, disc material and facet hypertrophy causing bilateral neuroforaminal narrowing that effaced the left and right L4 exiting nerve roots at L4-L5; diffuse disc protrusion with right preponderance and annular tear without effacing the thecal sac, disc material and facet hypertrophy causing narrowing of the right neural foramen that effaced the right L5 exiting nerve root at L5-S1. He has been treated with physical therapy and medication management. The date of UR decision was 2/10/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Unknown prescription of Terocin Patches: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 25, 60, 105, 111-113.

Decision rationale: Terocin is Capsaicin, Lidocaine, Menthol, Methyl Salicylate, and Boswellia Serrata. Per MTUS p112 with regard to capsaicin: "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Capsaicin has no indication for use on the head. Methyl Salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical Salicylate (e.g., Ben-Gay, Methyl Salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)." However, the other ingredients in Terocin are not indicated. The preponderance of evidence indicates that overall this medication is not medically necessary. Regarding topical Lidocaine, MTUS states (p112) "Non-neuropathic pain: Not recommended. There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995)." Per MTUS p25 Boswellia Serrata Resin is not recommended for chronic pain. Terocin topical lotion contains menthol. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually.

Prescription of compounded Ketoprofen 20% in PLO Gel, 120 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-112.

Decision rationale: With regard to topical Ketoprofen, the MTUS CPMTG states "This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure."As this agent is not FDA approved, it is not recommended. The MTUS supports topical NSAIDs for joint pain primarily, not for lower back pain. Medical necessity cannot be affirmed.

Prescription of compounded Cyclophene 5% in PLO Gel, 120 grams: Upheld

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

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

Decision rationale: Per MTUS p113 with regard to topical Cyclobenzaprine, "There is no evidence for use of any other muscle relaxant as a topical product." The evidence-based guidelines do not support the use of topical muscle relaxants. The request is not medically necessary.

Prescription of Synapryn 500ml, #1: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TRAMADOL, GLUCOSAMINE Page(s): 50, 78, 93, 113.

Decision rationale: Synapryn is Tramadol Hydrochloride and other proprietary ingredients in oral suspension with glucosamine. Per MTUS p50, glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee arthritis. Review of the submitted records does not indicate that the injured worker suffers from arthritis. Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveal neither documentation to support the medical necessity of Tramadol nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement,

appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) in the form of UDS were available; UDS report dated 2/13/14 was appropriate for prescribed medications. However, there is inadequate documentation comprehensively addressing the aforementioned concerns in the records available for my review. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

Prescription of Tabradol 250ml, #1: 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): 41-42.

Decision rationale: "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects."With regard to MSM, the MTUS redirects to DMSO and states "There is some evidence of efficacy for topical DMSO cream, IV Bisphosphonates and limited courses of oral corticosteroids" for the treatment of CRPS. While Cyclobenzaprine may be indicated for the injured worker's low back pain and spasm, note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The injured worker is not being treated for CRPS, MSM is not indicated. Medical necessity cannot be affirmed.

Prescription of Deprizine 250ml, #1: 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, GI SYMPTOMS & CARDIOVASCULAR RISK Page(s): 68.

Decision rationale: Deprizine is ranitidine hydrochloride and other proprietary ingredients in oral suspension. In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). CPMTG

guidelines further specify: "Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.)Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) or Misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44).Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is Naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)"As the injured worker's topical NSAID was not medically necessary, the request is also not medically necessary. Furthermore, as there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low, as such, medical necessity cannot be affirmed.

Prescription of Dicopanol 150ml, #1: 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 OFFICIAL DISABILITY GUIDELINES (ODG) PAIN (CHRONIC), INSOMNIA TREATMENT.

Decision rationale: Dicopanol is Diphenhydramine and other proprietary ingredients in oral suspension.Per ODG "Sedating antihistamines 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."The documentation submitted for review do not identify insomnia as a current problem, nor does it provide information regarding sleep onset, sleep maintenance, sleep quality or next day functioning to support the medical necessity of a sleep aid. The request is not medically necessary.

Prescription of Fanatrex 420ml, #1: 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): 16-18.

Decision rationale: Fanatrex is Gabapentin and other proprietary ingredients in oral suspension. Per MTUS CPMTG, "Gabapentin (Neurontin) has been shown to be effective for treatment of

diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain."Per MTUS CPMTG p17, "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 documentation submitted for review does not contain information supporting the continued use of this medication, specifically; functional improvement was not addressed in the medical records. Medical necessity cannot be affirmed.