

Case Number:	CM14-0029399		
Date Assigned:	06/20/2014	Date of Injury:	09/14/2013
Decision Date:	07/23/2014	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 and 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:

This 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 Utilization Review 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:

Prescription of Ketoprofen 20%, 120mg: 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 Page(s): 111-112.

Decision rationale: The California MTUS CPMTG states, Topical Ketoprofen, is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis 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 California MTUS supports topical NSAIDs for joint pain primarily, not for lower back pain. Therefore the request is not medically necessary.

Prescription of Cyclophene 5%, 120gm: Upheld

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

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

Decision rationale: The California MTUS states that there is no evidence for use regarding the topical Cyclobenzaprine or 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 10mg/ml oral suspension 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 Tramadol, Glucosamine Page(s): 50, 78, 93, 113.

Decision rationale: Synapryn is tramadol hydrochloride and other proprietary ingredients in oral suspension with glucosamine. The California MTUS states, 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 do not indicate that the injured worker suffers from arthritis. The California MTUS Chronic Pain Medical Treatment Guidelines states 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 no 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 California 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 not enough documentation comprehensively addressing the aforementioned concerns in the records available for my review. The California MTUS recommends to discontinue opioids if there is no overall improvement in function. Therefore the request is not medically necessary.

Prescription of Tabradol 1mg/ml oral suspension 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): 41-42.

Decision rationale: Tabradol is Cyclobenzaprine hydrochloride and other proprietary ingredients in oral suspension with MSM. The California MTUS states, Cyclobenzaprine is 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. Therefore, the request is not medically necessary.

Prescription of Deprizine 15mg/ml oral suspension 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, 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 California MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The California 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: 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 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. If 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. Therefore, the request is not medically necessary.

Prescription of Dicopanol 5mg/ml oral suspension 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 Official Disability Guidelines (ODG) Pain (Chronic), Insomnia Treatment.

Decision rationale: Dicopanol is diphenhydramine and other proprietary ingredients in oral suspension. The Official Disability Guidelines states, 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 25mg/ml oral suspension 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): 16-18.

Decision rationale: Fanatrex is gabapentin and other proprietary ingredients in oral suspension. The California MTUS CPMTG states that 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 and 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. Therefore, the request is not medically necessary.