MAXIMUS Federal Services

Case Number:	CM14-0118742		
Date Assigned:	08/06/2014	Date of Injury:	02/01/2012
Decision Date:	09/24/2014	UR Denial Date:	07/28/2014
Priority:	Standard	Application Received:	07/29/2014

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, has a subspecialty in Pain Medicine and is licensed to practice in Texas & Ohio. 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 32-year-old male with a reported injury on 02/01/2012. The mechanism of injury was while working as a kitchen worker he sustained cumulative-type injuries. His diagnoses consisted of left ankle pain, left ankle sprain/strain, rule out left ankle internal derangement, status post-acute osteomyelitis to the left ankle and foot, status post debridement of infection to the left ankle and foot, and left ankle injury. There was a lack of evidence of previous treatments such as therapy and the use of NSAIDs. The injured worker had an examination on 06/30/2014 with complaints of his left ankle and foot of constant to intermittent moderate to severe pain at a level of 7/10. The injured worker stated that his symptoms persisted, but the medications offered temporary relief of pain and improved his ability to have restful sleep. Upon examination of the left ankle/foot, it revealed that he had a well healing surgical scar on the left foot and there was no atrophy, edema, ecchymosis, effusion, or other deformities. There was tenderness to palpation over the surgical scar and there was normal range of motion. There was slightly decreased sensation to pinprick and by touch at the L4-S1 dermatomes bilaterally. The list of medications included cyclobenzaprine 5% cream, Synapryn, ketoprofen 20% cream, Tabradol, Deprizine, Dicopanol, and Fanatrex. The efficacy of those medications was not provided. The recommended plan of treatment was to use the medications. The request for authorization was signed and dated for 06/30/2014. The rationale was not provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobezaprine 5% cream 100gm: 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: The California MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many agents. California MTUS Guidelines also do not recommend any compounded product that contains at least 1 drug (or drug class) that is not recommended. Muscle relaxants are not recommended. There is no evidence for the use of any other muscle relaxant other than baclofen which is used for the treatment of chemotherapy-induced peripheral neuropathy. Furthermore, the request does not specify directions as far as duration, frequency, and the placement as to where to apply the product. The clinical information failed to provide the efficacy of the medication to support continued use or the presence of muscle spasms. There is a lack of evidence to support the medical necessity of this medication. Therefore, the request for cyclobenzaprine 5% cream is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78-80,84.

Decision rationale: The California MTUS Guidelines recommend for monitoring of opioids for there to be documentation of pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant or non-adherent drug-related behaviors. The efficacy of the medication was not provided. There were no complaints of side effects. There was a lack of evidence of physical or psychosocial functioning deficits and/or improvements. There was not a urine drug screen test provided to monitor for aberrant or non-adherent drug-related behaviors. Synapryn does have Tramadol which a recent review found that this drug decreased pain intensity, produced symptom relief, and improved function for a period of time of up to 3 months, but the benefits were small. There was a lack of evidence of efficacy of this medication and it is unknown as to how long the injured worker has been on this medication. Furthermore, there is a lack of rationale for an oral suspension versus a pill form of this medication. Additionally, the request does not specify directions as far as frequency, duration, and dosage. The clinical information fails to meet the evidence-based guidelines for this request. Therefore, the request for the Synapryn is not medically necessary.

Ketoprofen 20% cream 165gm: 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 analgesic Page(s): 111-112.

Decision rationale: The California MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many agents. California MTUS Guidelines also do not recommend any compounded product that contains at least 1 drug (or drug class) that is not recommended. Ketoprofen is a non-steroidal Anti-inflammatory agent. The efficacy in clinical trials for this treatment has been inconsistent and most studies are small and of short duration. This medication has been used at least since 06/2014. The efficacy of this medication was not provided. There is a lack of evidence of the medical necessity of this medication. Furthermore the request does not specify directions as to frequency, duration or placement to where to apply the product. Therefore, the request for ketaprofen 20% cream is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93-94, 113. Decision based on Non-MTUS Citation www.drugs.com, official disability guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

Decision rationale: The California MTUS Guidelines recommend muscle relaxants as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. This drug contains cyclobenzaprine and cyclobenzaprine is recommended for a short course of therapy. There is limited by mixed evidence that does not allow for recommendation of chronic use. The recommendation for this medication is it is not to be used for longer than 2 to 3 weeks. There is a lack of evidence of muscle spasms in the examination provided. The injured worker does not complain of low back pain. Furthermore, there is a lack of a rationale for an oral suspension versus a pill form of this medication. Additionally, the request does not specify directions as far as dosage, frequency, and duration. The clinical information fails to meet the evidence-based guidelines for this request. Therefore, the request for Tabradol 1 mg/1 ml oral suspension 250 ml is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

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

Decision rationale: The California MTUS Guidelines recommend this type of medication for injured workers that are at risk for gastrointestinal events such as over the age of 65, a history of

peptic ulcer, gastrointestinal bleed, or the concurrent use of aspirin, corticosteroids, and/or anticoagulants, or if they are on high doses or multiple doses of an NSAID. The injured worker is not over the age of 65 and there was no evidence of a history of peptic ulcer, gastrointestinal bleed, and perforation. There was not concurrent use of aspirin, corticosteroids, and/or anticoagulants. The injured worker is not on high doses or multiple NSAIDs. Furthermore, there were no complaints of gastrointestinal events such as nausea, vomiting, or diarrhea. There is a lack of a rationale for a suspension versus an oral pill form medication. There is a lack of evidence for the medical necessity of this medication. Therefore, the request for Deprizine 15 mg/ml oral suspension 250 ml is not medically necessary.

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, compound agents, antiemetic.

Decision rationale: The California MTUS Guidelines and the ACOEM Guidelines do not address this request. The Official Disability Guidelines do not recommend compounded drugs as a first-line of therapy. The criteria for compounded drugs need to include at least 1 drug substance that is the sole active ingredient in an FDA-approved prescription drug not including over-the-counter drugs; this medication's main ingredient is diphenhydramine which is an over-the-counter medication. It also includes an antiemetic which the Official Disability Guidelines recommend for nausea and vomiting. There is a lack of complaints of nausea and vomiting form the injured worker. There is a lack of a rationale to support oral suspension versus a pill form. Furthermore, there is a lack of directions as far as frequency, duration, and the dosage to be given. The clinical information fails to meet the evidence-based guidelines. Therefore, the request for the Dicopanol 5 mg oral suspension 150 mg is not medically necessary.

Fanatrex: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs Page(s): 16-22.

Decision rationale: The California MTUS Guidelines recommend anti-epilepsy drugs for neuropathic pain. The drug gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia. There is a lack of evidence that this injured worker has diabetic neuralgia and is having neuropathic pain. Furthermore, the directions do not specify dosing, or frequency, or duration, of this medication. There is a lack of evidence to support the medical necessity of this medication. Therefore, the request is not medically necessary.