

Case Number:	CM13-0059988		
Date Assigned:	03/03/2014	Date of Injury:	09/26/2013
Decision Date:	05/08/2014	UR Denial Date:	11/18/2013
Priority:	Standard	Application Received:	12/02/2013

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 Family Practice and is licensed to practice in Texas. 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 47-year-old male who reported injury on 09/26/2013. The mechanism of injury was noted to be the injured worker was unloading a pallet of windows, and it started to lean to the right, and a coworker got off to steady the windows, and called for help. The injured worker got to the forklift to move the pallet off the truck, and the truck driver started to pull away from the dock, and with the forklift half on the truck and half on the dock, the injured worker jumped off and tried to grab the fence to hold on, and slipped on the dock and landed on his right foot. The diagnosis of 11/15/2013 revealed the injured worker had dull, achy, sharp low back pain a 7/10 to 8/10 that was intermittent to frequency and moderate to severe at times. The injured worker indicated the symptoms persisted, but medications offered temporary relief of pain and improved the injured worker's ability to have restful sleep. The injured worker denied problems with medications. The diagnoses were noted to include lumbar spine sprain/strain, rule out HNP, rule out lumbar radiculopathy, status post closed fracture of the medial malleolus of the right ankle with residual pain, left ankle sprain/strain rule out internal derangement, and bilateral sprain/strain rule out internal derangement. The request was made for Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex, as well as ketoprofen and Cyclophene.

IMR ISSUES, DECISIONS AND RATIONALES

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

KETOPROFEN 20% PLO GEL 120 GRAMS: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: ACOEM GUIDELINES, LOW BACK, 308-310

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, TOPICAL ANALGESICS AND KETOPROFEN, PAGE 111 AND PAGE 112

Decision rationale: The California MTUS indicates topical analgesics 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. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period." Ketoprofen is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to document exceptional factors to warrant nonadherence to guideline recommendations. The duration for the use of the medication could not be established through the submitted documentation. The request as submitted failed to indicate the frequency for the medication. Given the above, the request for ketoprofen 20% PLO gel in 120 grams is not medically necessary.

CYCLOPHENE 5% PLO GEL 120 GRAMS: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308-310.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS; TOPICAL MUSCLE RELAXANTS; CYCLOBENZAPRINE Page(s): 111, 113, 41. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, TOPICAL ANALGESICS; TOPICAL MUSCLE RELAXANTS; CYCLOBENZAPRINE, PAGE 111, PAGE 113 AND PAGE 41

Decision rationale: California MTUS indicates 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 one drug (or drug class) that is not recommended is not recommended. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review failed to provide the necessity for 2 topicals with Cyclobenzaprine. This request was concurrently being reviewed with a request for Tabradol. There was a lack of documentation indicating the injured worker had neuropathic pain and that trials of antidepressants and anticonvulsants had failed. Additionally, the request as submitted failed to indicate the frequency for the medication, and there was an inability to establish the duration the injured worker had been on the medication. Given the above, the request for Cyclophene 5% POL gel in 120 grams 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, PAIN

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines GLUCOSAMINE SULFATE; ONGOING MANAGEMENT; TRAMADOL Page(s): 50, 78; 82; 93-94.

Decision rationale: California MTUS Guidelines recommend Tramadol for pain; however, do not recommend it as a first-line oral analgesic. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption. California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included Tramadol and glucosamine sulfate. Clinical documentation submitted for review failed to provide the necessity for an oral suspension which included Tramadol and glucosamine sulfate. There should be documentation of an objective improvement in function, an objective decrease in the patient's pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. Clinical documentation submitted for review failed to provide exceptional factors to warrant nonadherence to guideline recommendations. The clinical documentation submitted for review failed to indicate the duration the injured worker had been on the medication. Additionally, there was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The duration for the use of medication could not be established. The request as submitted failed to indicate a frequency. Given the above, the request for Synapryn 10 mg/mL oral suspension 500 mL is not medically necessary.

TABRADOL 1MG/1ML ORAL SUSPENSION 250ML: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CYCLOBENZAPRINE Page(s): 41.

Decision rationale: California MTUS indicate that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of Cyclobenzaprine to other agents is not recommended. They do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Tabradol is a compounding kit for oral suspension of Cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California MTUS guidelines and Official Disability Guidelines, along with the

National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence based literature for the oral compounding of Cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. The clinical documentation submitted for review failed to indicate the necessity for both a topical and oral form of Cyclobenzaprine. Additionally, there was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency for the medication. There was a lack of documentation indicating the duration for the use of the medication. Given the above, the request for Tabradol 1 mg/mL oral suspension 250 mL is not medically necessary.