

Case Number:	CM14-0017494		
Date Assigned:	04/14/2014	Date of Injury:	09/26/2013
Decision Date:	06/30/2014	UR Denial Date:	01/15/2014
Priority:	Standard	Application Received:	02/11/2014

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 Anesthesiology, has a subspecialty in 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:

The injured worker is a 47-year-old male who reported an injury on September 26, 2013. The mechanism of injury was not provided. The documentation of January 20, 2014 revealed that the injured worker had a dull aching pain in the low back as well as the knees and right ankle. It was indicated that the symptoms persisted, but the medications offered temporary relief of pain and improved his ability to have a restful sleep. There were no side effects. The injured worker's diagnoses included other vertebral disc displacement of lumbar region; rule out radiculopathy, lumbar region; patellar bursitis and tendonitis bilaterally; sprain of anterior cruciate ligament of bilateral knee; pain in bilateral knee; status post fracture of lower leg, including right ankle; and a short Achilles tendon on the left. The treatment plan included an MRI of the right ankle, an EMG (electromyogram)/NCV (Nerve conduction velocity) test of the bilateral lower extremities, medications and a referral to an orthopedic surgeon. The injured worker's medication history indicated that the injured worker had been taking the requested medications since November 2013.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUNDED CYCLOPHENE 5% IN PLO GEL, 120G: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112,113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, TOPICAL MUSCLE RELAXANTS, CYCLOBENZAPRINE Page(s): 111, 113, 41.

Decision rationale: The Chronic Pain Medical Treatment Guidelines 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. The Chronic Pain Medical Treatment Guidelines do not recommend the topical use of Cyclobenzaprine as a 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 indicated that the injured worker had been utilizing the medication since November 2013. There was a lack of documentation indicating a necessity for both an oral and topical form of the medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for compounded Cyclophene 5% in PLO gel 120 gm is not medically necessary. There was a lack of documentation indicating that the injured worker had a trial and failure of antidepressants and anticonvulsants. Additionally, there was a lack of documentation indicating the efficacy of the requested medication. The request for compounded Cyclophene 5% in PLO gel, 120g, is not medically necessary or appropriate

SYNAPRYN (10MG/1ML ORAL SUSPENSION) 500ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93, 94.

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

Decision rationale: The Chronic Pain Medical Treatment 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. The Chronic Pain Medical Treatment 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. There should be documentation of an objective improvement in function, an objective decrease in 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 the necessity for an oral suspension which included tramadol and glucosamine sulfate. 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 that the injured worker had osteoarthritis to support the necessity for glucosamine sulfate. Additionally,

the request as submitted failed to indicate the frequency for the requested medication. The clinical documentation submitted for review failed to indicate that the injured worker had objective improvement in function, an objective decrease in pain and evidence that the injured worker was being monitored for aberrant drug behaviors. There was documentation that the injured worker had no side effects. The request for Synapryn (10mg/1ml oral suspension) 500ml is not medically necessary or appropriate

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

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64.

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

Decision rationale: The Chronic Pain Medical Treatment Guidelines indicate that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than two to three weeks. The addition of cyclobenzaprine to other agents is not recommended. They do not recommend the topical use of Cyclobenzaprine as a 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, Chronic Pain Medical Treatment 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 that the injured worker had an inability to swallow or tolerate a pill. Additionally, there was a lack of documentation indicating a necessity for topical and oral cyclobenzaprine. The request as submitted failed to indicate the frequency for the requested medication. The request for Tabradol (1mg/ml oral suspension) 250ml is not medically necessary or appropriate.

COMPOUNDED KETOPROFEN 20 PERCENT IN PLO GEL, 120G TID 99070: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

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

Decision rationale: The Chronic Pain Medical Treatment Guidelines, indicates Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and any compounded product that contains at least one drug (or drug class) that

is not recommended is not recommended and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Ketoprofen is not currently FDA approved for a topical application. The clinical documentation indicated the injured worker had been utilizing the medication since November of 2013. There was a lack of documentation of the efficacy of the requested medication. The request as submitted failed to indicate the frequency. The request for compounded Ketoprofen 20 percent in PLO gel, 120g, is not medically necessary or appropriate