

Case Number:	CM13-0045057		
Date Assigned:	12/27/2013	Date of Injury:	03/29/2007
Decision Date:	02/28/2014	UR Denial Date:	10/02/2013
Priority:	Standard	Application Received:	10/30/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine and Cardiology 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 physician 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 patient is a 53-year-old male who reported an injury on 03/29/2007. The exact mechanism of injury was not provided. The patient was noted to be status post lumbar fusion with residual pain 7/10 to 8/10, frequent to constant, mild to moderate with numbness, tingling, and radiating pain to the bilateral lower extremities. The patient indicated the symptoms persisted but the medications offered temporary relief of the pain and an improved ability to have a restful sleep. The patient was noted to have decreased range of motion and a positive bilateral straight leg raise on the right at 20 degrees and left at 15 degrees. The patient was noted to have decreased motor strength and sensation. The diagnoses were noted to include status post lumbar spine fusion and lumbar spine radiculopathy. The request was made for medication refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound 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, Ketoprofen Page(s): 111,112.

Decision rationale: California MTUS indicates Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety ... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant non-adherence to FDA guideline recommendations as well as California MTUS Guidelines. Given the lack of recommendation of Ketoprofen, the request for Compound Ketoprofen 20% in PLO gel 120 grams is not medically necessary.

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, Cyclobenzaprine Page(s): 111,113.

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 a topical muscle relaxant, 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 exceptional factors to warrant non-adherence to Guideline recommendations. Given the above, the request for Compounded Cyclophene 5% in PLO gel 120grams is not medically necessary.

Synapryn 10mg/1ml 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 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. Clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. Additionally, California MTUS Guidelines

recommend documentation of the 4 A's for ongoing management for patients with chronic pain on opioids. This documentation should include the patient's analgesia, activities of daily living, adverse side effects, and aberrant drug taking behavior. The clinical documentation submitted for review failed to provide documentation of the 4 A's. Additionally, there is a lack of documentation indicating the patient has knee osteoarthritis pain. Given the above and the lack of documentation of exceptional factors as well as documentation of the 4 A's, the request for Synapryn 10mg 150ml is not medically necessary

Tabradol 1mg 250ml: Upheld

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

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. 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. Given the 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, Tabradol 1mg 250ml is not medically necessary.

Deprizine 15mg 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 Page(s): 69.

Decision rationale: California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the medication Deprizine includes ranitidine, which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. The clinical documentation submitted for review failed to provide the patient had signs and symptoms of dyspepsia. Additionally, it failed to provide the efficacy of the requested medication. Given the above, the request for Deprizine 15mg 250ml is not medically necessary.

Dicopanol 5mg: 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 www.drugs.com/ search term=Dicopanol

Decision rationale: Per Drugs.com, Dicopanol is diphenhydramine hydrochloride and it was noted this drug has not been found by the FDA to be safe and effective and the labeling was not approved by the FDA. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to FDA regulations. There was a lack of documentation of the quantity being requested. As such, the request for Dicopanol 5mg is not medically necessary.