

Case Number:	CM13-0013594		
Date Assigned:	09/26/2013	Date of Injury:	10/08/2011
Decision Date:	01/15/2014	UR Denial Date:	08/07/2013
Priority:	Standard	Application Received:	08/16/2013

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 Physical Medicine & Rehabilitation and is licensed to practice in Illinois. 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 54-year-old male who reported injury on 10/08/2011. The mechanism of injury was not provided. The patient was noted to have complaints of sharp neck pain and muscle spasms. The patient was noted to have decreased range of motion in the cervical spine and the left shoulder. The diagnoses were noted to include cervicgia, cervical spine radiculopathy, left shoulder AC joint separation, and left shoulder rotator cuff syndrome. The request was made for a prescription for compound ketoprofen 20% 120 grams, prescription for compound Cyclophene 5% 120 grams, a prescription for Synapryn 10 mg/mL oral suspension 500 mL, a prescription of Tabradol 1 mg per mL oral suspension 250 mL, a prescription for Deprizine 15 mg/mL oral suspension 250 mL, a decision for a prescription of Dicopanor 15 mg/mL oral suspension 150 mL, and a prescription for Fanatrex 25 mg/mL oral suspension 420 ml.

IMR ISSUES, DECISIONS AND RATIONALES

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

Request for prescription for compound Ketoprofen 20% 120g: 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 Page(s): 111.

Decision rationale: The California MTUS states, "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....Ketoprofen: This agent is not currently FDA approved for a topical application". Clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to FDA guidelines. Given the above, the request for prescription of compound ketoprofen 20% 120 grams is not medically necessary.

Request for prescription for compound Cyclophene 5% 120g: 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 Page(s): 113.

Decision rationale: Per the physician's documentation, Cyclophene is a compounded product, which includes Cyclobenzaprine hydrochloride. 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. Clinical documentation submitted for review failed to provide exceptional factors to warrant nonadherence to guideline recommendations. Given the above, the request for prescription for compound Cyclophene 5% 120 grams is not medically necessary.

Request for prescription for Synapryn 10 mg/ml oral suspension 500 ml: 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 Page(s): 49, 78, 93, & 94. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Synapryn Online Package Insert

Decision rationale: Synapryn per the online package insert included tramadol and glucosamine sulfate. California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. 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. 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. Additionally, California MTUS Guidelines recommend documentation of the 4 A's for ongoing management for patients with chronic pain on opioids. This documentation includes the patient's analgesia, activities of daily living, adverse side effects and aberrant drug taking behavior. Clinical documentation states that the medications offer temporary relief, however it fails to address the 4 A's. Given the above, the request for a prescription for Synapryn 10 mg/mL oral suspension 500 mL is not medically necessary.

Request for prescription of Tabradol 1 mg/ml oral suspension 250 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not cite any medical evidence for its decision.

Decision rationale: 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 is not medically necessary.

Request for prescription for Deprizine 15 mg/ml oral suspension 250 ml: 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 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. Clinical documentation submitted for review failed to provide the patient had signs and symptoms of dyspepsia; and therefore, failed to support the necessity of the requested medication. Given the above, the request for a prescription for Deprizine 15 mg/mL oral suspension 250 ml.

Request for prescription of Dicopanол 15 mg/ml oral suspension 150 ml: 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 Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Dicopanол>

Decision rationale: California MTUS/ACOEM Guidelines do not address Dicopanол. Official Disability Guidelines do not address Dicopanол. Per Drugs.com, Dicopanол 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. Given the above, the request for Dicopanol 15 mg/mL oral suspension 150 mL is not medically necessary.

Request for prescription for Fanatrex 25 mg/ml oral suspension 420 ml: 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 Page(s): 49. Decision based on Non-MTUS Citation
<http://www.drugs.com/search.php?searchterm=Fanatrex>

Decision rationale: California MTUS, ACOEM, and Official Disability Guidelines do not address Fanatrex. Per drugs.com, Fanatrex is noted to be an oral suspension of Gabapentin and has not been found to be FDA-safe and effective, and the labeling has not been approved by the FDA. Given the above, and the lack of documentation of exceptional factors to warrant non-adherence to FDA guidelines, the request for prescription for Fanatrex 25 mg/mL oral suspension 420 mL is not medically necessary.