

Case Number:	CM13-0036713		
Date Assigned:	12/13/2013	Date of Injury:	07/22/2008
Decision Date:	02/15/2014	UR Denial Date:	09/19/2013
Priority:	Standard	Application Received:	10/21/2013

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 Pulmonary Disease 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 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 48-year-old male who reported injury on 07/22/2008. The mechanism of injury was not provided. The patient's diagnosis was noted to be lumbago, and 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:

Compounded Ketoprofen 20% in 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 Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Ketoprofen Page(s): 111,112.

Decision rationale: The 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 1 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 exceptional factors to warrant non-adherence to FDA Guidelines, as well as California MTUS

Guidelines. Given the above, the request for Compounded Ketoprofen 20% in PLO gel, 120 grams is not medically necessary.

Compounded Cyclophene 5% in 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 Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 113.

Decision rationale: The 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. Given the above and the lack of documentation of exceptional factors, the request for compounded Cyclophene 5% 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 (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate Section, Ongoing Management , Tramadol Page(s): 50,78,82,93,94.

Decision rationale: Synapryn, per the online package insert included tramadol and glucosamine sulfate. California MTUS Guidelines recommend tramadol for pain; however, they 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 1 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 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 includes 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. There was a lack of documentation indicating the patient had knee osteoarthritis to support the use of this medication. Given the above and the lack of documentation of exceptional factors to warrant usage of this medication, the request for Synapryn 10mg/1ml oral suspension 500ml is not medically necessary.

Tabradol 1mg/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 Official Disability Guidelines (ODG)

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

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.

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 Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69.

Decision rationale: The 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 documentation of signs and symptoms of dyspepsia. Additionally, it failed to provide the efficacy of the requested medication. Given the above, the request for Deprizine 15mg/ml oral suspension 250ml is not medically necessary.

Dicopanor 5mg/ml oral suspension 150ml: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs website, Dicopanor

Decision rationale: Per Drugs.com, Dicopanor 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. As such, the request for Dicopanor 5mg/ml oral suspension 150ml is not medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS.
Decision based on Non-MTUS Citation Drug website, Fanatrex

Decision rationale: 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 25mg/ml oral suspension 420ml is not medically necessary.