

Case Number:	CM14-0013745		
Date Assigned:	02/26/2014	Date of Injury:	10/31/2012
Decision Date:	07/24/2014	UR Denial Date:	01/09/2014
Priority:	Standard	Application Received:	02/03/2014

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 Occupational 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 patient is a 40 year-old male who has filed a claim for lumbar spine sprain/strain and lumbar radiculopathy associated with an industrial injury date of October 31, 2012. Review of progress notes indicates neck pain associated with numbness and tingling of the bilateral upper extremities, and low back pain radiating to the bilateral lower extremities. Findings include tenderness over the cervical and lumbar regions. The patient had bilateral hernia surgeries with pain in the groins/lower pelvis and shooting pain to the testicles. Treatment to date has included topical analgesics, Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex. Utilization review from January 09, 2014 denied the requests for compounded ketoprofen 20% in PLO gel 120g, compounded cyclophene 5% in PLO gel 120g, Synapryn 10mg/1ml oral suspension 500ml, Tabradol 1mg/ml oral suspension 250ml, Deprizine 15mg/ml oral suspension 250ml, Dicopanol 5mg/ml oral suspension 150ml, and Fanatrex 25mg/ml oral suspension 420ml as there is no indication as to why these are necessary instead of conventional analgesic agents, and there is poor research to prove their efficacy.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Ketoprofen (30% in PLO Gel) 120grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen is not currently FDA-approved for topical application. It has an extremely high incidence of photocontact dermatitis. The submitted documentation does not outline the patient's treatment history. There is no documentation regarding intolerance to or failure of first-line pain medications. There is no discussion concerning the need for variance from the guidelines. Therefore, the request is not medically necessary.

Compounded Cyclophene (5% in PLO Gel) 120grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Cyclophene contains cyclobenzaprine hydrochloride and other proprietary ingredients. According to the Chronic Pain Medical Treatment Guidelines, ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. The submitted documentation does not outline the patient's treatment history. There is no documentation regarding intolerance to or failure of first-line pain medications. There is no discussion concerning the need for variance from the guidelines. Therefore, the request 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 website drugsdb.eu.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine - dailymed.nlm.nih.gov.

Decision rationale: The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the National Library of Medicine was used instead. A search of online resources revealed that Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit. Additionally, this drug has not been found by FDA to be safe and effective, and is not approved by the FDA. The submitted documentation does not outline the patient's treatment history. There is no documentation regarding intolerance to or failure of first-line pain medications. Furthermore, there is no clear rationale identifying why a compound/oral suspension (as opposed to the evidence based guidelines supported and

FDA approved non-compounded medication) is needed for this patient. Therefore, the request is not medically necessary.

Tabradol 250mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine - dailymed.nlm.nih.gov.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine - dailymed.nlm.nih.gov.

Decision rationale: Tabradol is cyclobenzaprine hydrochloride with MSM in oral suspension. The Chronic Pain Medical Treatment Guidelines state that cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is recommended as a short-course therapy. The effect is greatest in the first 4 days of treatment. The submitted documentation does not outline the patient's treatment history. There is no documentation regarding intolerance to cyclobenzaprine in tablet form. In addition, Methylsulfonylmethane (MSM) is not FDA approved. There is no discussion concerning the need for variance from the guidelines. Therefore, the request is not medically necessary.

Deprizine 250mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation website drugs.com.

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

Decision rationale: The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the website drugs.com was used instead. According to FDA, Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. The submitted documentation does not outline the patient's treatment history. There is no documentation regarding upper GI symptoms in this patient. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request is not medically necessary.

Dicopanol (Diphenhydramine) 150mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation website drugs.com.

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

Decision rationale: The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the website drugs.com was used instead. Dicopanil is diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. The submitted documentation does not outline the patient's treatment history. There is no documentation regarding issues with sleep, and there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request is not medically necessary.

Fanatrex (Gabapentin) 420mL: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-18.

Decision rationale: Fanatrex is gabapentin with other proprietary ingredients in oral suspension. Gabapentin is used to treat diabetic painful neuropathy and postherpetic neuralgia. The submitted documentation does not outline the patient's treatment history. However, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request is not medically necessary.