

Case Number:	CM13-0016604		
Date Assigned:	09/30/2013	Date of Injury:	12/17/2010
Decision Date:	01/24/2014	UR Denial Date:	08/06/2013
Priority:	Standard	Application Received:	08/26/2013

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, was fellowship trained in Cardiovascular Disease, 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:

This patient is a 51-year-old female who reported an injury on 12/17/10 due to repetitive motion. The documentation submitted for review indicates the patient is status post right shoulder arthroscopic partial labral resection, arthroscopic bursectomy, synovectomy and debridement of the rotator cuff, as well as resection of a subacromial spur and the distal clavicle with coplaning. The surgery was performed on 7/31/13. The patient was evaluated most recently on 9/16/13; notes detail that the patient had complaints of constant right shoulder pain status post surgery, as well as discomfort with radiation of symptoms to the hands and fingers. The patient is currently attending physical therapy twice a week, and continues to have neck pain, as well as numbness and tingling in the hands, right more than left. On physical examination, the patient had positive Tinel's signs on the right side, as well as positive Spurling's on the right side.

IMR ISSUES, DECISIONS AND RATIONALES

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

compounded Cyclobenzaprine, Gabapentin, and capsaicin, 120gm for 30 days: Upheld

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

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

Decision rationale: The California MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no research to support the use of many of these agents. Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended cannot be recommended as a compounded whole; therefore, the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The MTUS states that muscle relaxants are not recommended, as there is no evidence for their topical use; therefore, Cyclobenzaprine is not recommended. It also states that Gabapentin is not recommended, since there is no peer-reviewed literature to support its use. Furthermore, Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations of Capsaicin are generally available as a 0.025% formulation and a 0.075% formulation. However, there have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. While the documentation submitted for review indicates the patient has pain to the shoulder which persists following surgery, the current requested medication exceeds recommendation of the guidelines; the request is not medically necessary and appropriate.

compounded Ketoprofen and Ketamine, 120gm for 30 days: Upheld

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

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

Decision rationale: The California MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no research to support the use of many of these agents. Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended cannot be recommended as a compounded whole; therefore, the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The MTUS states Ketoprofen is a non-FDA-approved agent for topical application. It has an extremely high incidence of photocontact dermatitis. While the documentation submitted for review indicates the patient has right shoulder pain which persists following surgery, the request for a compounded topical cream containing Ketoprofen and

Ketamine is not supported by the guidelines; the request is not medically necessary and appropriate.