

Case Number:	CM14-0107375		
Date Assigned:	08/01/2014	Date of Injury:	06/25/2013
Decision Date:	11/03/2014	UR Denial Date:	06/19/2014
Priority:	Standard	Application Received:	07/10/2014

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, has a subspecialty in Internal 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 injured worker is a 38-year-old woman who presents to her primary treating physician for reevaluation on June 6 of 2014. She complains of intermittent right shoulder pain which is mild to occasionally moderate. Pain is worse with repetitive movement and overhead activity. The pain is well controlled with medication and she denies any side effects at this time. On physical examination, the injured worker is in no distress. Examination of the cervical spine was normal, just tenderness to palpation with spasms over the lumbar paraspinal muscles and tendons to palpation over the bilateral sacroiliac joints. The right shoulder has a well-heeled scar. There was no inflammation present. She has tenderness to palpation over the right deltoid muscle. She's unable to internally or externally rotate the right shoulder. Diagnoses are gastritis; cervical spine strain/strain with mild spasms; lumbar spine sprain/strain with mild spasms; right shoulder sprain/strain with clinical impingement; status post right shoulder surgery, rotator cuff tear; right carpal tunnel syndrome for nerve conduction studies January 13 of 2014; anxiety; depression; and insomnia.

IMR ISSUES, DECISIONS AND RATIONALES

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

Capsaicin/Flurbiprofen/Tramadol/Menthol/Camphor 240 GM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Topical analgesics

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Capsaisin Page(s): 111-113. Decision based on Non-MTUS Citation FDA guidelines. December 5th, 2006 News Release: Compounded Topical Anesthetic Creams Online Official Disability Guidelines (ODG); Topical analgesics

Decision rationale: Topical analgesics pursuant to the CA MTUS, Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They're primarily recommended for neuropathic pain with 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. Additionally, many agents are compounded as monotherapy or in combination with other medications for pain control such as nonsteroidal anti-inflammatory, opiates, local anesthetics etc. However, there is little to no research to support the use of many of these agents. If the compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical agents pursuant to the Official Disability Guidelines contain similar recommendations. The topical analgesics are not recommended and there is mixed evidence about whether compounding topical medications are more efficacious than a single medication. The FDA warns against the practice of compounding topical anesthetic creams. The guidelines specifically state that if one ingredient of a compound is not recommended, the entire compound is not recommended. Guidelines go on to state that if a compound agent is required, this should be clear knowledge of the specific analgesic effect of each agent and how it would be useful for a specific goal required. Medical documentation does not discuss any of the compounded topical products. There is no documentation showing the requesting physician has clear knowledge of each specific agent is being combined or what specific goal would be achieved by compounding these ingredients together. Specific to this compound, flubiprophen, is not FDA approved or guideline supported in topical form. Tramadol is also not guideline supported in topical form. Consequently, Capsaisin, Flurbiprophen, Tramadol, Menthol, Camphor are not medically necessary.

Cyclobenzaprine/Flurbiprofen 240 GM:

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Topical analgesics

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

Decision rationale: Topical analgesics pursuant to the CA MTUS, Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental with few controlled trials to determine efficacy and safety. They're primarily recommended for neuropathic pain with 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. The FDA warns against the practice of compounding topical anesthetic creams. The guidelines specifically state that if one ingredient of compound is not recommended, the entire compound is not recommended. Guidelines go on to state that if a compound agent is

required, this should be clear knowledge of the specific analgesic effect of each agent and how it would be useful for a specific goal required. Medical documentation does not discuss any of the compounded topical products. There is no documentation in the medical record showing the requesting physician has clear knowledge of each specific agent is being combined or what specific goal would be achieved by compounding these ingredients together. Specific to this compound, Flurbiprophen is not FDA approved guideline supported in the topical form. Additionally, Cyclobenzaprine is also not guideline supported in topical form. Consequently cyclobenzaprine/flurbiprophen are not medically necessary. Based on the clinical information in the medical record and the peer reviewed, evidence based guidelines, the compounded topical creams are not medically necessary.