

Case Number:	CM13-0024394		
Date Assigned:	06/06/2014	Date of Injury:	05/25/2011
Decision Date:	07/25/2014	UR Denial Date:	08/18/2013
Priority:	Standard	Application Received:	09/13/2013

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 Physical Medicine & Rehabilitation 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 45-year-old female who reported an injury 05/25/2011. The mechanism of injury was not provided within the medical records. The clinical note dated 07/29/2013 indicated diagnoses of shoulder internal derangement, rotator cuff syndrome, shoulder sprain/strain, cervical disc without radiculopathy, cervical radiculopathy, cervical sprain/strain, and insomnia. The injured worker reported left shoulder dull and aching pain rated 6- 8/10 without medications and 4- 5/10 with medications. The pain was aggravated with left shoulder movements or lifting, and it was relieved with medications and rest. The injured worker reported dull and aching pain with radiating pain to the left arm rated at 5/10 without medications and 2/10 with medications. The pain was aggravated with neck movement and was relieved with medications and rest. On physical examination of the cervical spine, there was tenderness and mild spasm palpable over the bilateral paracervical muscles and bilateral trapezius muscles with decreased cervical range of motion in all planes due to end range neck pain. Examination of the lumbar spine was normal. Examination of the shoulder revealed tenderness to palpation over the left acromioclavicular joint, left subacromial region, and left greater tubercle, as well as tenderness and myospasms palpable over the left rotator cuff muscle. The injured worker's impingement and supraspinatus test were both positive in the left shoulder. The injured worker had decreased left shoulder range of motion in all planes due to end of range left shoulder pain. The injured worker's prior treatments included diagnostic imaging and medication. The injured worker's medication regimen includes hydrocodone, alprazolam, omeprazole, naproxen, and Terocin lotion. The provider submitted a request for ketoprofen 20%, Capzasin 0.375% menthol cream with 2 refills. A request for authorization was not submitted for review to include the date the treatment was requested.

IMR ISSUES, DECISIONS AND RATIONALES

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

KETOPROFEN 20% CAPSAICIN 0.375% MENTHOL CREAM WITH TWO REFILLS:
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): 111-112.

Decision rationale: The request for Ketoprofen 20% Capsaicin 0.375% Menthol Cream with two refills is not medically necessary. The California MTUS guidelines state that transdermal compounds are largely experimental in use with few randomized controlled trials to determine efficiency or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. 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. Ketoprofen is a Non FDA-approved agent. It has an extremely high incidence of photocontact dermatitis. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Capsaicin is generally available as a 0.025% formulation primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain. 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. The documentation submitted did not indicate the injured worker had tried and failed antidepressants and anticonvulsants. In addition, ketoprofen is a non-FDA approved agent per the guidelines. A compounded product that contains at least 1 drug or drug class that is not recommended, is not recommended. Additionally, Capsaicin is indicated for postherpetic neuralgia and diabetic neuropathy and postmastetic pain. The documentation submitted did not indicate the injured worker had findings that would indicate she had postherpetic neuralgia, diabetic neuropathy, or postmastetic pain. Additionally, Capsaicin is generally available as a 0.025% formulation. The formulation of 0.037% exceeds the guideline recommendations. Furthermore, the request does not indicate a quantity or frequency for the medication. Therefore, the request for ketoprofen 20%, Capsaicin 0.375% menthol cream with 2 refills is not medically necessary.