

Case Number:	CM14-0052289		
Date Assigned:	07/07/2014	Date of Injury:	02/13/2013
Decision Date:	08/25/2014	UR Denial Date:	04/01/2014
Priority:	Standard	Application Received:	04/21/2014

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 Internal Medicine and is licensed to practice in Arizona. 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:

This is a 29-year-old male who was injured on the job on two occasions. He was evaluated by a physiatrist, February 24, 2014 and illicit the following history. Sometime in 2010, he slipped off the bottom of the [REDACTED] delivery truck with his left hand holding onto a rail and had immediate soreness in his left shoulder. It did not dislocate, but he was diagnosed with a torn labrum. He underwent surgery in 2010 and was able to return to work in 2011. In November 2012, while reaching at work tone developed left shoulder pain. He had a left shoulder arthroscopy on May 31, 2013 and underwent debridement of the labrum, a subacromial decompression, and distal clavicle resection. He did well postoperatively. He had nine sessions of physical therapy. He had a mini functional capacity evaluation where he was able to lift 64 pounds from the floor to waist. He needs to be able to lift 70 pounds in order to return. Supplier stated he did not want the employee to return it lasts but in a percent. The patient believes he is at an 85% level. The physiatrist stated the complainant was highly motivated to initiate work hardening so that he can return to working comfortably without pain. He is on no medications. The physiatrist suggested a trial of using a Medrox patch on the left shoulder. He documented that it had Capsaicin, Methyl salicylate and Lidoderm, when in fact is comprised of 5% Menthol and .0375% Capsaicin.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective (dispensed: 02/54/2014) Medrox patch (duration and frequency unknown) for the treatment of the left shoulder: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 California Code of Regulations, 9792.20-9792.26, Topical Analgesics Page(s): 111, 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UpToDate, Methyl salicylate and menthol: Drug information U.S. Food and Drug Administration, Topical Pain Relievers May Cause Burns, posted Sept 13, 2012.

Decision rationale: Medrox is a topical analgesic consisting of 5% Menthol and .0375% Capsaicin. According to the MTUS, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. These 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 mono therapy or in combination for pain control (including non-steroidal anti-inflammatory drugs (NSAIDs), opioids, capsaicin, local anesthetics, antidepressants, etc. 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 (page 111). Capsaicin .025% can be used in persons with osteoarthritis. It is recommended only as an option in patients who have not responded or are intolerant to other treatments. He has benefited from physical therapy; but was not quite up to 100%. The records indicate that this patient has not taken any other medications, so it is not clear if a trial of anti-inflammatories might provide benefit. There have been no studies of a 0.0375% Capsaicin formulation (contained within the Medrox patch) and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The Menthol and Methyl salicylate are not mentioned in the MTUS, or ODG. UpToDate describes the combined duo's usage as providing temporary relief of minor aches and pains of muscle and joints associated with arthritis, bruises, simple backache, sprains, and strains. UpToDate lacks data on its efficacy. The FDA website however, indicated that there had been more than 43 reported cases of burns associated with the use of OTC topical muscle and joint pain relievers containing the active ingredients menthol, methyl salicylate and capsaicin. These cases were uncovered by FDA scientists during safety surveillance of FDA's adverse event reporting database and the medical literature. Furthermore, a majority of the more severe burns occurred with the use of a menthol or menthol/methyl salicylate combination product. Most of these cases involved products that contain higher concentrations of menthol and methyl salicylate (greater than 3% menthol or 10% methyl salicylate). Few of the cases involved Capsaicin. The Medrox patch containing 5% Menthol has the potential of causing skin problems and there are no known studies which indicate if there is benefit. The .0375% Capsaicin has a higher than needed concentration to benefit the patient. For all these reasons, this Medrox patch is found not medically necessary.