

Case Number:	CM13-0025681		
Date Assigned:	01/03/2014	Date of Injury:	09/07/2012
Decision Date:	05/30/2014	UR Denial Date:	09/13/2013
Priority:	Standard	Application Received:	09/17/2013

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 Internal Medicine & Emergency Medicine and is licensed to practice in Florida. 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 patient is a 44 year-old with a date of injury of 09/07/12. A progress report associated with the request for services, dated 09/09/13, identified subjective complaints of low back and elbow pain. Objective findings included tenderness to palpation of the left lateral elbow. Lumbar spine findings were negative including lack of tenderness as well normal motor and sensory function. Diagnoses included lumbar strain and lateral epicondylitis. Treatment has included physical therapy. A Utilization Review determination was rendered on 09/13/13 recommending non-certification of "Medrox patch #30 and Lenza gel 120gm".

IMR ISSUES, DECISIONS AND RATIONALES

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

MEDROX PATCH #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines PHYSICAL MEDICINE Page(s): 28-29; 105; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain: Topical Analgesics; Salicylate Topical.

Decision rationale: menthol USP 5%. The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that

they 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." The Chronic Pain Guidelines do recommend topical Salicylate as being significantly better than placebo in chronic pain. In osteoarthritis, Salicylate is superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical Salicylate as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither Salicylate nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Capsaicin is an active component of chili peppers and acts as an irritant. The Guidelines for Chronic Pain state that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. It is further noted that the 0.025% formulation is available for treatment of osteoarthritis and the 0.075% formulation for neuropathic pain. They state that there have been no studies of the 0.0375% formulation and no current indication that the increase over the 0.025% formulation would provide any further efficacy. The Official Disability Guidelines (ODG) states that neither Salicylate nor capsaicin has shown any efficacy in the treatment of osteoarthritis. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of menthol for chronic pain. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation, Medrox.

LENZA GEL 120GM: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Topical Analgesics.

Decision rationale: Lenza topical contains the active ingredients menthol and lidocaine. The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they 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." Menthol is used as a topical form of cryotherapy due to its cooling effects. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of menthol for chronic pain. Lidocaine is a topical anesthetic. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation.