

Case Number:	CM14-0083951		
Date Assigned:	07/21/2014	Date of Injury:	05/05/2014
Decision Date:	12/05/2014	UR Denial Date:	05/30/2014
Priority:	Standard	Application Received:	06/05/2014

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 Family 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:

This 39-year-old ironer reported an injury to her low back due to repeatedly pushing and pulling a boiler room door on 5/5/14. Initial treatment included medications and chiropractic treatment. Her current primary treater initially saw her on 5/27/14. The provider documented complaints of constant mild to moderate lumbosacral pain. Exam findings included tenderness, limited back range of motion, positive SLT (SLR?) bilaterally, and positive Patrick test bilaterally. Strength and sensation were normal. Diagnoses included lower back pain, sprain/strain of sacroiliac ligament, lumbosacral sprain/strain, and GERD (gastro-esophageal reflux disease). Naproxen, cyclobenzaprine, omeprazole and Lidopro ointment were dispensed, and a back brace was requested. No medical rationale for the ointment or brace was documented. The patient was advised to continue chiropractic manipulation. The Lidopro ointment and back brace were non-certified in UR on 5/30/14. Subsequent clinical notes through 11/7/14 reveal that the patient has not recovered as expected, remains at modified duty, and is now being followed for pain management. There has been no change in work restrictions from the initial visit on 5/27/14 through the most recent visit on 11/7/14. The restrictions include no lift/pull/push over 10 lbs, and "must wear splint", which I presume to mean back brace, as no other splint has been requested.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidopro topical ointment: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 49. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter, Topical Analgesics

Decision rationale: Lidopro ointment is a compounded preparation that contains capsaicin, lidocaine, menthol, and methyl salicylate. The ACOEM reference cited above states that topical medications are not recommended for initial treatment. The ODG guideline 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin is recommended as an option in patients who have not responded to or are intolerant to other treatments. There is no evidence supporting formulations which contain over 0.025% capsaicin. It has been shown to have some efficacy in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. Lidocaine is indicated for localized neuropathic pain if there is evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). Only FDA-approved products are indicated, and no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical lidocaine is not indicated for non-neuropathic pain. The clinical findings in this case do not support the use of Lidopro ointment. Use of this ointment means that three medications are being started simultaneously. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional improvement that might result. For this reason alone, this ointment is not medically indicated. Topical medications are not indicated for acute pain. This ointment contains 0.0325% capsaicin, which is higher than the percentage supported by evidence. There is no evidence that the patient has neuropathic pain, or that there has been any trial of an appropriate antidepressant or AED, so topical lidocaine is not indicated for this patient. In addition, the only FDA-approved form of topical lidocaine is the Lidoderm patch. This ointment is therefore not FDA approved, and automatically not medically necessary. Based on the evidence-based citations above and the medical information provided for my review, Lidopro ointment is not medically necessary. It is not medically necessary because its use means that three medications are being started simultaneously, because topical medications are not indicated for acute pain conditions, because its concentration of capsaicin exceeds that for which there is supporting evidence, and because topical lidocaine is not medically indicated for this patient and the lidocaine is in a form that is not FDA-approved.

Back Brace: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301 AND 308. Decision based on Non-MTUS Citation Other Medical Treatment

Guideline or Medical Evidence: ACOEM Guidelines, Update 4/7/08, Low Back Chapter, lumbar supports

Decision rationale: The ACOEM references state that lumbar supports have not been shown to have any lasting benefit beyond acute symptom relief, and that corsets are not recommended for treatment of low back conditions. The updated ACOEM Low Back chapter states that lumbar supports are not recommended. The use of a support for pain may theoretically speed healing, but numerous studies have shown a clear pattern of decreasing back pain with increasing activity. Thus a device that reduces mobility may actually be harmful. The clinical records do not support the provision of a back brace to this patient. The treating physician has documented no compelling reason for providing a back brace to this patient. Given that the patient appears to have been unable to increase her activity level, the back brace may actually have interfered with her healing process by limiting her movement. Based on the evidence-based citations above and the clinical information provided for my review, a back brace is not medically necessary for this patient because the treating physician did not document any compelling reason for its use, and because its use may have prevented increasing mobility and healing.