

Case Number:	CM14-0087254		
Date Assigned:	07/23/2014	Date of Injury:	06/04/2009
Decision Date:	04/21/2015	UR Denial Date:	05/21/2014
Priority:	Standard	Application Received:	06/10/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: Ohio, North Carolina, Virginia
 Certification(s)/Specialty: Family Practice

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 57 year old male, who sustained an industrial injury on June 4, 2009. He reported a sharp pain and muscle pull on the lower back along with pain in the bilateral shoulders, bilateral knees and left wrist. The injured worker was diagnosed as having degenerative disc disease with retrolisthesis L1-2, L2-3, moderate canal stenosis L1-2, bilateral neural foraminal narrowing moderate L4-5, lumbar radiculopathy, persistent general orthopedic complaints, cervical degenerative disc disease with myofascial strain and cervical radiculopathy. Treatment to date has included diagnostic studies, corset, cane, epidural injection, acupuncture, physiotherapy and medication. On March 5, 2015, the injured worker complained of low back pain. He rated his low back pain as a 4 on a 1-10 pain scale. He also reported right leg pain rated a 7/10 on the pain scale. This pain is described as stabbing and cramping. Symptoms are onset with prolonged walking, sitting, bending forward or rising from a seated position. Neck pain was also reported and rated as a 4/10 on the pain scale. The neck pain is aching and stabbing with radiation up to his head and bilateral shoulders. He complains of muscle tightness in the bilateral trapezius regions and frequent headaches. His neck pain increases with quick motion of the neck or with extension and flexion of the neck. He has difficulty sleeping at night due to his pain. The treatment plan included pain management follow-ups, internal medicine follow-ups, interlaminar epidural injection targeting C5-6, home exercises, walking cane and follow-up visit.

IMR ISSUES, DECISIONS AND RATIONALES

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

LidoPro Topical Ointment # 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111, 112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

Decision rationale: The referenced guidelines state that any compounded product containing at least one non-recommended ingredient is not recommended in its entirety. Lidopro cream contains lidocaine, menthol, capsaicin, and methyl salicylate has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% 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. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. Lidopro cream consists of capsaicin, lidocaine, menthol, and methyl salicylate. The only approved form of lidocaine is in the form of a patch (Lidoderm). Because the lidocaine portion of Lidopro is in a non-recommended form, the entire compound is therefore not recommended. Hence, Lidopro topical ointment is not medically necessary.