

Case Number:	CM14-0050122		
Date Assigned:	07/07/2014	Date of Injury:	03/31/2009
Decision Date:	08/21/2014	UR Denial Date:	04/10/2014
Priority:	Standard	Application Received:	04/17/2014

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:

The patient is a 51 year-old female who was injured at work on 3/31/2009. The injury was primarily to her right hand, low back and left knee. She is requesting review of medical necessity of Terocin Ointment. Medical records corroborate ongoing treatment for her chronic pain. The Primary Treating Physician's Progress Reports (PR-2s) are included and indicate that her diagnoses include: osteoarthritis of the right wrist, left knee strain, lateral meniscus tear, status post partial medial meniscectomy, carpal tunnel syndrome, cervical sprain, lumbar sprain, and sprain of the abdominal wall. In addition to receiving prescriptions for Motrin and Flexeril, she received a prescription for Terocin Ointment. Terocin Ointment is listed with the following ingredients: Lidocaine, Capsaicin, and Menthol Methyl Salicylate.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin ointment 120ml: Upheld

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

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

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of Topical Analgesics. The use of these medications is considered as largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) 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. (Colombo, 2006) 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). (Argoff, 2006) 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. Two of the components in Terocin Ointment (Lidocaine and Capsaicin) have additional comments in the MTUS Guidelines.

Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there 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. (Scudds, 1995)

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. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) There is no evidence presented in the medical records that the intent of the

prescription for Terocin Ointment is in the treatment of a neuropathic cause of this patient's pain. Further, there is no evidence that the patient has undergone trials with antidepressants or anticonvulsants. In summary, based on the stated guidelines, there is no medical justification for the use of Terocin Ointment. It is not a medically necessary treatment.