

<b>Case Number:</b>	CM14-0198658		
<b>Date Assigned:</b>	12/08/2014	<b>Date of Injury:</b>	06/11/2013
<b>Decision Date:</b>	01/21/2015	<b>UR Denial Date:</b>	11/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2014

### 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 40 year-old man who was injured at work on 6/10/2013. The injury was primarily to his back, shoulders, neck and extremities. He is requesting review of denial for treatment with a compounded cream: i.e. Ketoprofen/Gabapentin/Lidocaine Cream #240 grams. Medical records corroborate ongoing care for his injuries. These records include the Primary Treating Physician's Progress Reports. These reports indicate that his chronic diagnoses include the following: Cervical/Lumbar/Thoracic Sprain & Strain with Radiculopathy; and Tendonitis/Bilateral Shoulders. As of 11/6/2014 the patient's medication list includes Lyrica 100 mg, Senokot-S 50/8.6 mg, Tramadol 50 mg, and the Ketoprofen/Gabapentin/Lidocaine compounded cream. Utilization review was performed on 11/6/2014. MTUS guidelines regarding topical analgesics were cited as the justification for denial. Specifically, that Ketoprofen was not approved for topical application.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen/Gabapentin/Lidocaine compounded cream #240gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Compounded Drugs

**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 as a treatment modality. Topical analgesics are recommended as an option as indicated below. As a group they are considered as 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. 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. There is little to no research to support the use of many of these agents. The guidelines specifically state "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended the guidelines comment on the use of specific agents as topical analgesics".

**Non-steroidal anti-inflammatory agents (NSAIDs):** The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder.

**Neuropathic pain:** Not recommended as there is no evidence to support use.

**FDA-approved agents:** Voltaren Gel 1% (Diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus.

**Non FDA-approved agents:** Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis.

**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.

**Gabapentin:** Not recommended. There is no peer-reviewed literature to support use. In this case the requested compounded cream has two agents that are not recommended per the MTUS guidelines. Specifically, Ketoprofen and Gabapentin are not recommended. Ketoprofen, as noted above has an extremely high incidence of photo contact dermatitis. Gabapentin is not recommended as there is no peer-reviewed literature to support its use. Under these conditions and the MTUS recommendation that "Any compounded product that contains at least one drug (or drug class) that is not recommended is

not recommended," the compounded cream with Ketoprofen/Gabapentin/Lidocaine is not medically necessary.