

<b>Case Number:</b>	CM14-0021902		
<b>Date Assigned:</b>	05/09/2014	<b>Date of Injury:</b>	01/26/2011
<b>Decision Date:</b>	12/02/2014	<b>UR Denial Date:</b>	02/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/21/2014

### 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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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 injured worker is a 61 year old male with an original date of injury on 1/26/2011. The mechanism of injury was jumping off a forklift from 3 feet off the ground leading to pain in right hip, neck, and lower back. The patient's industrially related diagnoses include cervical strain, lumbar degenerative disc disease, and impingement of the right hip with anterosuperior labral tear. MRI of the hip completed on February 23, 2011 showed a tear of the anterior superior labrum and femoral acetabular impingement. A MRI of the lumbar spine completed on January 18, 2012 revealed impingement of the exiting right L5 nerve root, disc space loss, right foraminal protrusion with marked overgrowth of the facet joint and broad-based protrusion at L4-5 without evidence of stenosis. An electromyogram and nerve conduction study data on September 13, 2013 indicated there was bilateral L5-S1 radiculopathy. His current medications include Norco 2.5mg twice daily, Naproxen 550mg twice daily, Gabapentin 300mg three times daily, Flurbiprofen 20% and Lidocaine 2% cream, and Mentherm cream. The disputed issues are for the refill of Flurbiprofen 20% and Lidocaine 2% cream, and Mentherm Cream 120mg (1 tube). A utilization review determination on 2/19/2014 had noncertified these requests. The stated rationale for the denial was no documentation of significant change in VAS score, pain, or functional improvement with the continued use of the requested medications. Per utilization review, the use of topical and compound medication has not been shown to result in superior systemic blood levels versus appropriately used oral medications in FDA approved dosages. As the claimant is clearly able to tolerate oral medications, there is no rationale presented for the use of compound cream. Therefore, these requests are not certified.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retro Flurbiprofen 20% and Lidocaine 2% cream:** 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 (NSAIDs, Lidocaine) Page(s): 112-113.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on page 112 state the following: "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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) 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. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: 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."The Chronic Pain Medical Treatment Guidelines on pages 112-113 specific the following regarding topical 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)".The patient was started on Flurbiprofen 20% and Lidocaine 2% cream on November 14, 2013. The medication was continued through January 3, 2014, where a progress note documented patient getting refill of the medication from his provider. While being

on the requested medication, a progress note from January 3, 2014 documents patient having pain scale 10 out of 10 which is brought on with activities such as bending, lifting, twisting, prolonged standing, prolonged sitting, getting out of cars and chairs, sneezing, walking, and coughing. Exam findings suggest decreased range of motion of the lumbar spine secondary to pain and paraspinal muscle spasm. There is lack of evidence that Flurbiprofen 20% and Lidocaine 2% cream has helped with this patient's function or pain scale. According to the guidelines, topical NSAIDs shows very little evidence in helping with hip and spine area pain. In addition, the guidelines states topical Lidocaine is not typically recommended for non-neuropathic pain. Therefore, this request is not medically necessary.

**Retro Mentherm cream 120mg x1 tube:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topical Page(s): 105.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 112.

**Decision rationale:** Mentherm is a topical formulation of Methyl Salicylate and Menthol. The Chronic Pain Medical Treatment Guidelines on page 111 states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Thus, each active ingredient should be analyzed in making a determination of medical necessity. The Chronic Pain Medical Treatment Guidelines on page 112 state the following: "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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) 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. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: 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."The patient was started on Mentherm cream on the same day as he was started Flurbiprofen 20% and Lidocaine 2% cream on November 14, 2013. The medication was continued through January 3, 2014, where a progress note documented patient getting refill of the medication from his provider. Based on the provided documentation, there is lack of evidence that this medication has helped with this patient's function or pain scale. In addition, the guidelines recommend a short term use of 4-12 weeks of which the patient has already completed. The patient has no contraindication to oral NSAIDs. Therefore, this request is not medically necessary.

