

<b>Case Number:</b>	CM15-0185841		
<b>Date Assigned:</b>	09/28/2015	<b>Date of Injury:</b>	02/28/2008
<b>Decision Date:</b>	11/10/2015	<b>UR Denial Date:</b>	08/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/21/2015

### 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: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 49 year old female who sustained an industrial injury on 02-28-2008. The injured worker was diagnosed with rotator cuff sprain and strain, cervical degenerative disc disease, cervical disc displacement without myelopathy and brachial neuritis or radiculitis (not otherwise specified). The injured worker has a medical history of gastroesophageal reflux disorder (GERD). The injured worker is status post right rotator cuff repair in 2011. According to the treating physician's progress report on 08-21-2015, the injured worker complained of abdominal pain radiating to the right thigh and rated at 7 out of 10 on the pain scale. The injured worker states medications are helping and are tolerated well with side effects of dizziness, nausea and vomiting. The injured worker ambulates with an antalgic gait without assistive devices. Cervical spine examination demonstrated tenderness of the right paravertebral muscles and restricted range of motion with extension to 20 degrees. The right shoulder range of motion was restricted by pain with flexion to 40 degrees. Sensory examination noted decreased light touch over the medial and lateral right hand. The right hip examination demonstrated restricted range of motion due to pain with extension limited to 40 degrees. Tenderness was noted over the right sacroiliac joint. There was increased pain with lumbar flexion and extension. Motor testing was limited by pain. Right hip flexors were 3 out of 5, knee flexors and extensors were 4 out of 5 and right hip abduction was 4 out of 5. Left side power was within normal limits. Prior treatments included diagnostic testing, right shoulder injections, surgery, physical therapy and medications. Current medications were listed as Cyclobenzaprine, Gabapentin, Tylenol ES, Famotidine, Terocin Patch and LidoPro ointment. Treatment plan consists of follow-up

orthopedic appointment, continuing medication regimen, remain on temporary total disability (TTD) and the current retrospective request for LidoPro ointment 4.5%-27.5%-0.0325%-10% #1 (DOS: 8-21-15) and the retrospective request for Terocin patch 4-4% #1 (DOS: 8-21-15). On 08-27-2015 the Utilization Review determined the request for the retrospective request for LidoPro ointment 4.5%-27.5%-0.0325%-10% #1 (DOS: 8-21-15) and the retrospective request for Terocin patch 4-4% #1 (DOS: 8-21-15) were not medically necessary.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Retrospective Terocin patch 4-4% #1 (DOS 8/21/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** Terocin is capsaicin, lidocaine, menthol, methyl salicylate, and boswellia serrata. Per MTUS p 112 "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." Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)" However, the other ingredients in Terocin are not indicated. The preponderance of evidence indicates that overall this medication is not medically necessary. Regarding topical lidocaine, MTUS states (p112) "Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). 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)" Per MTUS p25, Boswellia Serrata Resin is not recommended for chronic pain. Terocin patches contain menthol. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The

recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. The request is not medically necessary.

**Retrospective Lidopro ointment 4.5%-27.5%-0.0325%-10% #1 (DOS 8/21/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. LidoPro contains capsaicin, lidocaine, menthol, methyl salicylate. Per MTUS p 112 with regard to capsaicin, "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." Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)" However, the other ingredients in LidoPro are not indicated. The preponderance of evidence indicates that overall this medication is not medically necessary. Regarding topical lidocaine, MTUS states (p112) "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). 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 documentation submitted for review does not contain evidence of trial of first-line therapy to support the use of topical lidocaine. LidoPro topical lotion contains menthol. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request is not medically necessary.