

<b>Case Number:</b>	CM14-0132545		
<b>Date Assigned:</b>	08/27/2014	<b>Date of Injury:</b>	06/15/1997
<b>Decision Date:</b>	09/29/2014	<b>UR Denial Date:</b>	08/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/19/2014

### 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 Anesthesia, has a subspecialty in Acupuncture & 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:

This 59 year old male injured worker with date of injury 6/15/97 with related right shoulder pain. Per progress report dated 7/21/14, the injured worker was not seen by the primary treating physician for a few months. The injured worker reported that the last MRI (12/2013) revealed biceps tendon inflammation in the extra-articular aspect with some evidence of previous AC joint resection. There was some tendinosis along the rotator cuff noted. Per physical exam, there was right shoulder tenderness along biceps tendon and rotator cuff with positive findings of impingement. The documentation submitted for review did not state whether physical therapy was utilized. He has been treated with TENs unit, and medication management. The date of Utilization Review (UR) decision was 8/13/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Terocin Patches, thirty count:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Inflammatory Medications Section and NSAIDs (non-steroidal anti-inflammatory drugs), Specific Drug List and Adverse Effects Section Page(s): 22 and 70. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Diclofenac.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 25,60,105,111-113.

**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) "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, The request is not medically necessary and appropriate.

**Lidopro cream, four ounces, one bottle:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**Decision rationale:** 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. 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.