

<b>Case Number:</b>	CM14-0068799		
<b>Date Assigned:</b>	07/14/2014	<b>Date of Injury:</b>	09/12/2013
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	04/17/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/13/2014

### 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 is a 22 year old female injured worker with date of injury 9/12/13 with related right wrist/hand pain. Per progress report dated 4/25/14, the injured worker reported numbness and tingling and rated her pain 8/10 without medication, and 0/10 with oral medications. She stated that topical medications decreased her pain and increased her sleep. Per physical exam, her right upper extremity had decreased sensation at C6-C8. Her diagnoses included status post right thumb laceration, and right carpal tunnel syndrome. Imaging studies were not available for review. She has been treated with physical therapy and medication management. The date of UR decision was 4/17/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 Terocin 240mg (Capsaicin 0.025%, Methyl Salicylate 25%, Menthol 10% and Lidocaine 2.5%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints, Chronic Pain Treatment Guidelines Topical analgesics.

**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. Capsaicin does not appear to have an indication in this context. 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 (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica)." Per MTUS p25 Boswellia Serrata Resin is not recommended for chronic pain. Terocin 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. Furthermore, the documentation submitted for review contains no evidence of a trial of first-line therapy for neuropathic pain. 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.

**1 Flurbi (NAP) Cream-LA 180 grams (Flurbiprofen 20%, Lidocaine 5%, and Amitriptyline 4%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints, Chronic Pain Treatment Guidelines Topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 60, 111-112. Decision based on Non-MTUS Citation Topical Analgesics in the Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205).

**Decision rationale:** Per MTUS with regard to Flurbiprofen (p112), "(Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies

of their effectiveness or safety." Flurbiprofen may be indicated. Per the article "Topical Analgesics in the Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205), "Studies in healthy volunteers demonstrated that topical amitriptyline at concentrations of 50 and 100 mmol/L produced a significant analgesic effect ( $P < .05$ ) when compared with placebo and was associated with transient increases in tactile and mechanical nociceptive thresholds." Amitriptyline may be indicated. With regard to lidocaine MTUS p 112 states "Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica)." The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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,  $\alpha$ -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." 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 documentation submitted for review contains no evidence of a trial of first-line therapy for neuropathic pain, as such, topical lidocaine is not indicated. The request is not medically necessary.