

<b>Case Number:</b>	CM13-0060034		
<b>Date Assigned:</b>	01/29/2014	<b>Date of Injury:</b>	11/15/2011
<b>Decision Date:</b>	06/12/2014	<b>UR Denial Date:</b>	10/23/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/02/2013

### 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 Analgesics & 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 case involves a 46-year-old male injured worker with date of injury of 11/15/11, with related complaints in his neck, bilateral shoulders, upper back, and lower back. He has been diagnosed with cervical sprain; impingement syndrome in the bilateral shoulders, left more than the right with possible rotator cuff tears; chronic strain of lumbar with radicular pain to the left buttock and left posterior thigh. An electromyogram dated 10/2/13, revealed findings suggestive of chronic L5 nerve root irritation on the left side; no electrophysiological evidence of entrapment neuropathy on the peroneal, and tibial nerves; no electrophysiological evidence to support distal peripheral neuropathy in the lower extremities. He was treated with chiropractic therapy, physical therapy, epidural steroid injections, and medication management. The date of utilization review (UR) decision was 10/23/13.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**RETROSPECTIVE REQUEST FOR FLURBIPROFEN 10% #120, APPLY TWO TO THREE (2-3) TIMES A DAY ON THE SITE OF PAIN FOR SIX (6) REFILLS:** 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 Page(s): 111-112.

**Decision rationale:** In regards to Flurbiprofen, the Chronic Pain Guidelines indicate that "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety." However, the guidelines do not require documentation of significant pain reduction, or functional improvement to warrant the continued use of topical analgesics. The request is medically necessary.

**RETROSPECTIVE REQUEST FOR KETOPROFEN 15%+LIDOCAINE  
1%+TRAMADOL 5%: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN (UPDATED 10/14/2013), COMPOUND DRUGS.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-112.

**Decision rationale:** In regards to topical Ketoprofen, the Chronic Pain guidelines indicate that "This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis." With regard to lidocaine, the Chronic Pain guidelines indicate that "Further research is needed to recommend this treatment for chronic neuropathic pain disorders and other than post-herpetic neuralgia" and "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." The injured worker has not been diagnosed with post-herpetic neuralgia. Lidocaine is not indicated. The Chronic Pain Guidelines states 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. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\hat{I}\pm$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\hat{I}\beta$  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, the guidelines state "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. 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. Since ketoprofen and lidocaine are not indicated, the compound is not recommended. This request is not medically necessary.

**RETROSPECTIVE REQUEST FOR CAPSAICIN (NATURAL) 0.0125% #60, APPLY ONE TO THREE (1-3) TIMES A DAY TO THE SITE OF PAIN REFILL #6:** Overturned

**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 Page(s): 111-112.

**Decision rationale:** The Chronic Pain guidelines indicate that topical capsaicin "Recommended only as an option in patients who have not responded or are intolerant to other treatments...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." The guidelines do not require documentation of significant pain reduction, or functional improvement to warrant the continued use of topical analgesics. The injured worker has exhausted conventional therapy, and is using this treatment along with other modalities, the request is medically necessary.

**RETROSPECTIVE REQUEST FOR CYCLOBENZAPRINE 2%+CAPSAICIN (NATURAL) 0.0125%+LIDOCAINE 1%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN (UPDATED 10/14/2013), COMPOUND DRUGS.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-112.

**Decision rationale:** According to the Chronic Pain Guidelines with regard to topical cyclobenzaprine, "There is no evidence for use of any other muscle relaxant as a topical product." Topical cyclobenzaprine is not indicated. The guidelines also indicate that topical capsaicin is "Recommended only as an option in patients who have not responded or are intolerant to other treatments...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." Topical capsaicin may be indicated. With regard to lidocaine, the guidelines state "Further research is needed to recommend this treatment for chronic neuropathic pain disorders and other than post-herpetic neuralgia" and "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 injured worker has not been diagnosed with post-herpetic neuralgia. Lidocaine is not indicated. The Chronic Pain 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." 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. 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,  $\beta$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). 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, the guidelines state "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 one (1) week. A record of pain and function with the medication should be recorded. 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 give a trial to each medication individually. Since cyclobenzaprine and lidocaine are not indicated, the compound is not recommended. The request is not medically necessary.