

<b>Case Number:</b>	CM14-0080005		
<b>Date Assigned:</b>	07/18/2014	<b>Date of Injury:</b>	04/20/2001
<b>Decision Date:</b>	11/12/2014	<b>UR Denial Date:</b>	05/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/30/2014

### 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 Family Medicine and is licensed to practice in North Carolina. 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 patient is a 64-year-old with a reported date of injury of 04/20/2001. The patient has the diagnoses of pain in shoulder joint, lumbago and pain in lower leg. Previous treatment modalities have included left shoulder arthroscopy, left knee TKA and bilateral knee arthroscopy. Per the most recent progress notes provided for review by the primary treating physician dated 04/16/2014, the patient had complaints of chronic low back, lower extremity and shoulder pain. The physical exam noted no specific abnormalities. The treatment plan recommendations included functional restoration program and medication modification/continuation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **Retrospective Pharmacy Purchase of Capsalcin 60gm #120: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines capsaicin Page(s): 28-29.

**Decision rationale:** The California chronic pain medical treatment guidelines section on capsaicin states: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025%

formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. 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 number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) The results from this RCT support the beneficial effects of 0.025% capsaicin cream as a first-line therapy for OA pain. (Altman, 1994) Mechanism of action: Capsaicin, which is derived from chili peppers, causes vasodilation, itching, and burning when applied to the skin. These actions are attributed to binding with nociceptors, which causes a period of enhanced sensitivity followed by a refractory period of reduced sensitivity. Topical capsaicin is superior to placebo in relieving chronic neuropathic and musculoskeletal pain. Capsaicin produces highly selective regional anesthesia by causing degeneration of capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds. (Maroon, 2006) Adverse reactions: Local adverse reactions were common (one out of three patients) but seldom serious (burning, stinging, erythema). Coughing has also been reported. See also CRPS, medications; Topical analgesics. This medication is only recommended in patients with documentation of failure or intolerance to other first-line treatment options. This patient has had therapeutic failure with Topamax, Effexor and Gabapentin. Therefore criteria for the use of the medication have been met and the request is medically necessary.

**Retrospective Pharmacy Purchase of Ketamine 5% 60gm x 120: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. 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, 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. Ketamine: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also Glucosamine (and Chondroitin Sulfate).The requested medication is indicated for neuropathic pain. The patient does have the diagnosis of neuropathic pain. The patient has failed anticonvulsants, muscle relaxants, surgical intervention and antidepressants therapy for control of the pain. For these reasons, criteria as set forth by the California MTUS have been met for the use of this medication. Therefore the request is medically necessary.