

<b>Case Number:</b>	CM13-0034693		
<b>Date Assigned:</b>	12/11/2013	<b>Date of Injury:</b>	01/25/2013
<b>Decision Date:</b>	02/03/2014	<b>UR Denial Date:</b>	09/10/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/15/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Orthopedic Surgery, 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 physician 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 claimant is a 50-year-old gentleman who was injured in a work related accident on January 25, 2013. He sustained injury to his neck, low back, lower extremities and bilateral shoulders. Recent clinical reports for review include an April 11, 2013 assessment with [REDACTED], a board certified orthopedic surgeon, who gave the claimant diagnoses of: 1. Chronic cervical spine strain. 2. Chronic lumbar spine strain. 3. Left shoulder rotator cuff tear. He indicated subjectively the claimant continued to be with discomfort about the neck, bilateral shoulders and low back. His examination findings demonstrated restricted cervical and lumbar range of motion, with equal and symmetrical deep tendon reflexes and a normal upper extremity sensory examination and lower extremity examination also not demonstrating neurologic finding. The claimant's shoulders were with left greater than right restricted motion with 5/5 strength with the exception of left shoulder flexion, extension and abduction. There was noted to be tenderness over the subacromial space and AC joints bilaterally. The recommended treatment on that date was for an MRI scan of the left shoulder, cervical spine and lumbar spine, a urine drug screen and prescriptions for diclofenac as well as Bio Therm cream. Records indicate that Bio Therm cream is Capsaicin. Prior imaging includes an MRI report of September 11, 2013 of the cervical spine showing diffuse disc bulging with multilevel mild spinal stenosis from C4-5 through C6-7 with a 2 millimeter diffuse disc bulge at C6-7 and a lumbar MRI scan performed on the same date that showed disc desiccation with a grade I spondylolisthesis of L5 on S1 with a central disc bulge at L3-4.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Decision for BIOTHERM:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** Per the MTUS Guidelines, BIOTHERM is 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,  $\hat{I}\pm$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\hat{I}^3$  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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic<sup>®</sup> (fentanyl transdermal system).] Capsaicin: 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) See also Capsaicin. Therefore, based on California MTUS Chronic Pain Medical Treatment Guidelines, the role of Bio Therm in this case would not be indicated. As stated above, Bio Therm contains .02% Capsaicin. Capsaicin is only recommended as an option for claimants who are intolerant or who have not responded to other forms of first line treatment and modalities. The role of this agent without documenta