

<b>Case Number:</b>	CM15-0144271		
<b>Date Assigned:</b>	08/05/2015	<b>Date of Injury:</b>	10/09/2006
<b>Decision Date:</b>	08/31/2015	<b>UR Denial Date:</b>	07/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/24/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: North Carolina

Certification(s)/Specialty: Family Practice

### 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 injured worker is a 63-year-old male with an industrial injury dated 10-09-2006. The injured worker's diagnoses include thoracic muscle spasms and posterior lumbar fusion, L2-S1, Dynesys stabilization in 2008. Treatment consisted of diagnostic studies, prescribed medications, and periodic follow up visits. In a progress note dated 07-08-2015, the injured worker reported mid- thoracic spasms, left worse than right. Objective findings revealed mild tenderness to palpitation with spasm of the left greater than right mid-thoracic paraspinous muscles, pain with extension of the lumbar spine, mild bilateral weakness, decrease sensation of left lateral thigh, and absent deep tendon reflexes at the left Achilles. X-ray of the lumbar spine dated 07-08-2015 revealed intact hardware with mild spondylosis above fusion without evidence of fracture or instability. The treatment plan consisted of medication management and physical therapy. The treating physician prescribed Flector 1.3% #60, Carisoprodol -Soma 350mg #90 and physical therapy (lumbar) 2x6 weeks, now under review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector 1.3% #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics.

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

**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. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study, the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) Topical analgesic NSAID formulations are not indicated for long-term use and have little evidence for treatment of the spine, hip or shoulder. This patient does not have a diagnosis of osteoarthritis or neuropathic pain that has failed first line treatment options. Therefore criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.

**Carisoprodol / Soma 350mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines- Treatment in Workers' Compensation Pain Procedure Summary last updated 06/15/2015, muscle relaxants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-65.

**Decision rationale:** The California chronic pain medical treatment guidelines section on muscle relaxants states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) (Chou, 2004) This medication is not intended for long-term use per the California MTUS. The medication has not been prescribed for the flare-up of chronic low back pain. This is not an approved use for the medication. For these reasons, criteria for the use of this medication have not been met. Therefore, the request is not medically necessary.

**Physical therapy (lumbar) 2x6 weeks: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines physical medicine Page(s): 98-99.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines physical medicine Page(s): 98-99.

**Decision rationale:** The California chronic pain medical treatment guidelines section on physical medicine states: Recommended as indicated below. Passive therapy (those treatment modalities that do not require energy expenditure on the part of the patient) can provide short term relief during the early phases of pain treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They can be used sparingly with active therapies to help control swelling, pain and inflammation during the rehabilitation process. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy may require supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices. (Colorado, 2002) (Airaksinen, 2006) Patient-specific hand therapy is very important in reducing swelling, decreasing pain, and improving range of motion in CRPS. (Li, 2005) The use of active treatment modalities (e.g., exercise, education, activity modification) instead of passive treatments is associated with substantially better clinical outcomes. In a large case series of patients with low back pain treated by physical therapists,

those adhering to guidelines for active rather than passive treatments incurred fewer treatment visits, cost less, and had less pain and less disability. The overall success rates were 64.7% among those adhering to the active treatment recommendations versus 36.5% for passive treatment. (Fritz, 2007)Physical Medicine Guidelines Allow for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home Physical Medicine. Myalgia and myositis, unspecified (ICD9 729. 1): 9-10 visits over 8 weeks. Neuralgia, neuritis, and radiculitis, unspecified (ICD9 729. 2) 8-10 visits over 4 weeks. Reflex sympathetic dystrophy (CRPS) (ICD9 337. 2): 24 visits over 16 weeks. The goal of physical therapy is graduation to home therapy after a certain amount of recommended sessions. The request is in excess of these recommendations per the California MTUS. There is no objective reason why the patient would not be moved to home therapy after completing the recommended amount of supervised sessions in the provided clinical documentation. Therefore, the request is not medically necessary.