

Case Number:	CM15-0181842		
Date Assigned:	09/23/2015	Date of Injury:	03/31/2014
Decision Date:	10/28/2015	UR Denial Date:	09/15/2015
Priority:	Standard	Application Received:	09/15/2015

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:

This is a 61 year old female with a date of injury of March 31, 2014. A review of the medical records indicates that the injured worker is undergoing treatment for lumbar annular tear, lumbar myofascitis, lumbar radiculitis, and right shoulder pain. Medical records dated July 20, 2015 indicate that the injured worker complains of lumbar spine pain rated at a level of 7 out of 10 that radiates to the left leg with numbness and tingling, and right shoulder pain rated at a level of 10 out of 10 with radiation to the right hand. Records also indicate that the back pain is associated with prolonged sitting and supine position, that the right shoulder pain is aggravated by any movement, and that the injured worker's pain had increased since the last visit. A progress note dated August 11, 2015 notes subjective complaints of constant lower back pain rated at a level of 8 out of 10 with stiffness, numbness, and tingling radiating to the bilateral hips with numbness and tingling, and constant right shoulder pain rated at a level of 9 out of 10 with radiation to the right hand with numbness, tingling, and weakness. Per the treating physician (August 11, 2015), the employee has not returned to work. The physical exam dated July 20, 2015 reveals tenderness to palpation of the left sacroiliac joint, pain with Kemp's, left pain with straight leg raise, tenderness to palpation of the right anterior shoulder, pain with supraspinatus press, and pain with shoulder apprehension. The progress note dated August 11, 2015 documented a physical examination that showed decreased range of motion of the lumbar spine, tenderness to palpation of the left sacroiliac joint, pain with Kemp's, left pain with straight leg raise, decreased range of motion of the right shoulder, tenderness to palpation of the right anterior shoulder, pain with supraspinatus press, and pain with shoulder apprehension. Treatment has included acupuncture, and medications (Gabapentin-Amitriptyline-Bupivacaine and Flurbiprofen- Baclofen-Dexamethasone-Capsaicin since at least May of 2015). The original utilization review (September 15, 2015) non-certified a request for Flector patches #90 and Soma 350mg #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flector patches #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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 photocontact 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 but rather the diagnosis of back and shoulder pain. Therefore criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.

Soma 350mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

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, but rather for ongoing and chronic back and shoulder 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.