Case Number:	CM15-0162471		
Date Assigned:	08/28/2015	Date of Injury:	04/23/2010
Decision Date:	09/30/2015	UR Denial Date:	07/31/2015
Priority:	Standard	Application Received:	08/18/2015

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 62 year old female, who sustained an industrial injury on April 23, 2010, incurring upper back, upper extremity, left chest wall and left shoulder injuries after a slip and fall. She was diagnosed with chronic cervicalgia, cervical radiculopathy, recurrent myofascial strain, and bilateral upper extremity radiculopathy. Cervical Magnetic Resonance Imaging revealed multilevel degenerative disc disease. Treatment included pain medications, neuropathic medications, topical analgesic creams, and activity restrictions. Currently the injured worker complained of chronic neck and bilateral upper extremity pain with limited range of motion and persistent muscle spasms. The treatment plan that was requested for authorization included prescriptions for Diclofenac Sodium cream and Ketamine cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac sodium 1.5% 60 grams #1: Upheld

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

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.

Ketamine 5% cream 60 grams #1: Upheld

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

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. The requested medication contains ingredients (Ketamine only indicated for CRPS), which are not indicated per the California MTUS for topical analgesic use. Therefore, the request is not medically necessary.