

Case Number:	CM15-0085920		
Date Assigned:	05/12/2015	Date of Injury:	05/06/2004
Decision Date:	06/29/2015	UR Denial Date:	04/07/2015
Priority:	Standard	Application Received:	05/05/2015

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: California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 64 year old male, who sustained an industrial injury on 05/06/2004. The initial complaints or symptoms included gradual onset of pain in the cervical spine, bilateral shoulders, bilateral arms, wrist and hands, low back pain, and bilateral legs and ankles from repetitive tasks. The initial complaints and diagnoses were not mentioned in the clinical notes. The diagnoses include cervical spine musculoligamentous strain/sprain, rule out herniated nucleus pulposus with bilateral upper extremity radicular pain, lumbar spine musculoligamentous strain/sprain, rule out herniated nucleus pulposus with bilateral lower extremity radiculopathy, bilateral shoulder musculoligamentous strain/sprain, bilateral ankle musculoligamentous strain/sprain, bilateral wrist musculoligamentous strain/sprain, insomnia, gastroesophageal reflux disease, headaches, dizziness, anxiety and depression. Comorbid conditions include diabetes, atrial fibrillation and obesity (BMI 32). Treatment to date has included conservative care, medications, cardiac testing, x-rays, CT scans, MRIs, conservative therapies, injections to the shoulders and psychological therapy. Currently, the injured worker complains of cervical spine pain, bilateral shoulder pain, bilateral arm pain, bilateral wrist/hand pain, lumbar spine pain, bilateral leg pain and bilateral ankle pain. Objective findings included tenderness to palpation of the cervical, thoracic and lumbar spines, and bilateral shoulders and wrist. There was positive findings of the following test: Spurling's and cervical compression tests bilaterally; Hoffman's on the left; impingement, arm drop, Neer's and Hawkin's tests bilaterally; Phalen's and reverse Phalen's test bilaterally; and straight leg raise, Braggard's and Bowstring tests bilaterally. Other positive findings included sensory deficits over the bilateral C6 and

median nerve distribution below the mid forearm and over the bilateral S1 dermatomes, upper extremity motor weakness bilaterally, lower extremity motor weakness bilaterally, and decreased reflexes.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren XR 100mg #30 (prescribed 03/16/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory drugs. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Diclofenac, Diclofenac sodium.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Klinge SA, Sawyer GA. Effectiveness and safety of topical versus oral non-steroidal anti-inflammatory drugs: a comprehensive review. Phys Sportsmed. 2013 May;41(2):64-74.

Decision rationale: Voltaren (diclofenac) is a non-steroidal anti-inflammatory medication (NSAID). The XL version of this medication is formulated for once per day dosing. NSAIDs as a group are recommended for treatment of osteoarthritis and for short-term use in treating symptomatic pain from joint or muscle injury. In fact, MTUS guidelines notes that studies have shown use of NSAIDs for more than a few weeks can retard or impair bone, muscle, and connective tissue healing and perhaps even cause hypertension. However, if used, diclofenac must be used cautiously in patients with heart disease as research has shown use of this medication is associated with an increased risk of cardiac events. Head-to-head studies of oral NSAIDs with topical NSAIDs suggest topical preparations should be considered comparable to oral NSAIDs and are associated with fewer serious adverse events. Use of a topical NSAID would be a safer choice for this patient than oral diclofenac due to this patient's heart disease. Additionally, this patient has had stable chronic pain for over 12 weeks and thus can be considered past the point where NSAIDs should be of value in treatment unless used short-term for exacerbation of the patient's chronic injuries. The records do not show instructions to the patient for use of this medication only for exacerbations. Given all the above information medical necessity for use of this medication has not been established. The request is not medically necessary.

Flurbiprofen 20% cream 120gm (prescribed 03/16/15): Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Non-steroidal anti-inflammatory agents.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs); Topical Analgesics Page(s): 67-73, 111-13. Decision based on Non-MTUS Citation Klinge SA, Sawyer GA. Effectiveness and safety of topical versus

oral non-steroidal anti-inflammatory drugs: a comprehensive review. Phys Sportsmed. 2013 May;41(2):64-74.

Decision rationale: Flurbiprofen cream is a non-steroidal anti-inflammatory (NSAIDs) medication formulated for topical use. The systemic form of this medication is indicated for treatment of mild to moderate pain. Topical NSAIDs have been effective in short-term use trials for chronic musculoskeletal pain but long-term use has not been adequately studied. In general, the use of topical agents to control pain is considered an option by the MTUS although it is considered largely experimental, as there is little to no research to support their use. Although most topical analgesics are recommended for treatment of neuropathic pain, topical NSAIDs are primarily recommended for treatment of osteoarthritis and tendonitis. This patient has been diagnosed with cervical and lumbar sprains, suggesting a tendonitis is present. However, the patient is already taking an oral NSAID preparation. Head-to-head studies of oral NSAIDs with topical NSAIDs suggest topical preparations should be considered comparable to oral NSAIDs and are associated with fewer serious adverse events, specifically gastrointestinal reactions. Since the present NSAID the patient is using has significant cardiac risks and this patient has known cardiac disease, use of a topical NSAIDs is best for patient safety. Medical necessity for use of this preparation has been established. The request is medically necessary.

Ketoprofen 20%/Ketamine 10% cream 120gm (prescribed 03/16/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Non-steroidal anti-inflammatory agents.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ketamine; NSAIDs (non-steroidal anti-inflammatory drugs); Topical Analgesics] Page(s): 56, 67-72, 111-13.

Decision rationale: Ketoprofen-ketamine cream is a combination product formulated for topical use. It is made up of ketoprofen, a non-steroidal anti-inflammatory (NSAID) medication, and ketamine, an anesthetic. The systemic form of ketoprofen is indicated for treatment of mild to moderate pain. Topical NSAIDs have been effective in short-term use trails for chronic musculoskeletal pain but long-term use has not been adequately studied. The MTUS does not recommend the use of ketamine to treat chronic pain. In general, the use of topical agents to control pain is considered an option by the MTUS although it is considered largely experimental, as there is little to no research to support their use. They are primarily recommended for the treatment of neuropathic pain. It is important to note the MTUS states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Since ketamine is not recommended for topical use, this product is not recommended. Medical necessity for use of this product has not been established. The request is not medically necessary.

Gabapentin 10%/Cyclobenzaprine 10%/Capsaicin 0.0375% cream 120gm (prescribed 03/16/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Non-steroidal anti-inflammatory agents.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), Capsaicin Topical, Cyclobenzaprine, Muscle Relaxants, Topical Analgesics Page(s): 16-22, 28-9, 41-2, 63-6, 111-13.

Decision rationale: Gabapentin-Cyclobenzaprine-Capsaicin Cream is a combination product formulated for topical use. It is made up of gabapentin, an anticonvulsant and analgesic, Cyclobenzaprine, a muscle relaxant, and capsaicin, a topical analgesic. The use of topical agents to control pain is considered an option although it is considered largely experimental, as there is little to no research to support their use. They are primarily recommended for the treatment of neuropathic pain when first line agents such as antidepressants or antiepileptics have failed. Even though the MTUS describes use of gabapentin as an effective medication in controlling neuropathic pain, it does not recommend its use topically. The MTUS does not address the topical use of cyclobenzaprine but notes that when used systemically, cyclobenzaprine use should be brief (no more than 2-3 weeks) and not combined with other medications. Capsaicin is a capsaicinoid compound with analgesic properties indicated for the temporary relief of minor aches and pains of muscles and joints and to reduce the symptoms of a peripheral neuropathy. It has also been used to treat the itching and inflammation caused by psoriasis. When compared to a placebo, its use has been superior in relieving chronic neuropathic pain and musculoskeletal pain. The MTUS recommends its use as option for treating pain in patients intolerant to other treatments. It is important to note the MTUS states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Since gabapentin is not recommended for topical use as there is no evidence of effectiveness, this product is not recommended. Medical necessity has not been established for use of this medication. The request is not medically necessary.