

<b>Case Number:</b>	CM15-0004171		
<b>Date Assigned:</b>	01/16/2015	<b>Date of Injury:</b>	03/19/2002
<b>Decision Date:</b>	04/06/2015	<b>UR Denial Date:</b>	12/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/08/2015

### 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: Montana

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 57 year old female, who sustained an industrial injury on 3/19/2002. The mechanism of injury was not noted. The diagnoses have included degeneration of cervical intervertebral disc, brachial plexus injury, left shoulder pain with MRI evidence for rotator cuff tear, neuritis and radiculitis. Treatment to date has included surgical and conservative measures. Medications have included Norco, Opana ER and Soma. Electromyogram/Nerve Conduction Studies to the upper extremities (1/30/2014) were normal. Magnetic resonance imaging left shoulder, post arthrogram (9/12/2014), noted evidence of prior rotator cuff repair, possible partial or complete tear of the supraspinatus tendon, and moderate degenerative changes of the acromioclavicular joint. Currently, the injured worker complains of left upper extremity pain. Physical exam of the left upper extremity noted positive Adson's and Tinel's test. Tenderness to palpation was noted at the left pectoralis minor and left trapezius with muscle twitch response. On 12/26/2014, Utilization Review non-certified a prescription request for Voltaren Gel 1% #5. Specified Guidelines for the decision were not noted.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Voltaren Gel 1% # 5:** 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 based on Non-MTUS Citation Official Disability Guidelines (ODG), Voltaren Gel.

**Decision rationale:** Voltaren gel is a topical analgesic containing diclofenac, a nonsteroidal anti-inflammatory (NSAID) drug. The MTUS recommends topical analgesics primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. They are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics have been shown to have some benefit in the first 2 weeks of treatment for osteoarthritis but with diminishing effect after that. 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. Topical analgesics containing nonsteroidal anti-inflammatory agents are recommended only as a short-term option for chronic musculoskeletal pain associated with arthritis and tendinitis but there is little evidence for use in osteoarthritis or musculoskeletal pain involving the spine, hip or shoulder. It is also not recommended for neuropathic pain. Efficacy in clinical trials has been inconsistent with most studies being small and of short duration. There are no long-term studies of their effectiveness or safety. The FDA has approved Voltaren Gel 1% (diclofenac) with indications 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). Additional adverse effects for NSAIDs include GI symptoms, cardiovascular risk, hypertension and impaired renal function. The ODG guidelines note that Voltaren Gel is not recommended as a first-line treatment. Voltaren Gel is recommended for osteoarthritis after failure of an oral NSAID, or contraindications to oral NSAIDs, or for patients who cannot swallow solid oral dosage forms, and after considering the increased risk profile with diclofenac, including topical formulations. According to FDA MedWatch, postmarketing surveillance of Voltaren Gel has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. In this case the use of Voltaren Gel is not consistent with the MTUS and ODG guidelines. It is recommended only for short term use. There has been no documented trial of antidepressant or anticonvulsant medications and no failure of oral NSAIDs. It is not recommended for the shoulder joint and not recommended for neuropathic pain or radiculopathy. The request for Voltaren Gel 1% #5 is not medically necessary.