

<b>Case Number:</b>	CM14-0210064		
<b>Date Assigned:</b>	12/23/2014	<b>Date of Injury:</b>	02/25/2009
<b>Decision Date:</b>	02/19/2015	<b>UR Denial Date:</b>	12/04/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/15/2014

### 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 has a date of injury of 2/25/09 with no mechanism of injury documented in the medical records provided. She continues to complaint of low back pain radiating to the lower extremities, primarily on the right. She does have a past history of lumbar surgery in 1996 and 1998. Physical examination has shown tenderness to palpation in the lumbar area without documentation of muscle spasm. Electrodiagnostic testing has demonstrated right S1 radiculopathy. Current diagnoses are low back pain with lumbar postlaminectomy syndrome, lumbar radiculitis and degenerative disc disease. The records show that epidural steroid injection has been requested and that injections in the past have been beneficial. Medications used have included Voltaren gel, hydrocodone, tizanidine, cyclobenzaprine, ketoprofen and a trial of Lyrica. The primary treating physician has requested tizanidine 2 mg #60 with 1 refill, Voltaren Gel 1% 2 g with 1 refill, and hydrocodone/APAP 5/325 #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tizanidine 2mg #60 x 1 refill:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-spasmodics/anti-spasticity drugs Page(s): 63 AND 66.

**Decision rationale:** The MTUS notes that muscle relaxants are recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases they show no benefit beyond nonsteroidal anti-inflammatory drugs in pain and overall improvement. Efficacy does appear to diminish over time. Sedation as the most commonly reported adverse effect of muscle relaxant medications. The MTUS notes that Tizanidine (Zanaflex) is a centrally acting alpha 2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. Eight studies have demonstrated efficacy for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome. It may also provide benefit as an adjunct treatment for fibromyalgia. The usual initial doses 4 mg, titrated gradually by 2-4 mg every 6-8 hours until therapeutic effect, maximum 36 mg per day. Comments side effects including somnolence, dizziness, dry mouth, hypotension, weakness and hepatotoxicity. Liver function tests should be monitored at baseline and at 1,3, and 6 months. In this case the medical records show that tizanidine has been used since at least June 2014 without documentation of significant muscle spasm in the treatment records. There is no documentation of clinical efficacy or functional improvement for this medication. The current request is for a one-month supply with 1 additional refill. This clearly is not consistent with the short-term use of muscle relaxants recommended by the MTUS. If tizanidine is intended to be used on a more long-term basis, functional improvement related to its use must be documented and liver function tests should be considered as recommended above. The request for tizanidine 2 mg #60 with 1 refill is not medically necessary.

**Voltaren topical 1% gel 2g x 1 refill:** 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 Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Voltaren Gel

**Decision rationale:** Voltaren gel is a topical analgesic containing diclofenac, a non-steroidal 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 non-steroidal 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 gastrointestinal (GI) symptoms, cardiovascular risk, hypertension and impaired renal function. The Official Disability Guidelines (ODG) 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, post-marketing 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 has been since at least June 2014. It is recommended for short-term use for chronic musculoskeletal pain associated with arthritis and tendinitis. There is little evidence for efficacy regarding spinal conditions. Continued use is not consistent with the MTUS and ODG guidelines. Therefore, this request is not medically necessary.

**Hydrocodone/APAP 5/325mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75-80 and 91.

**Decision rationale:** Hydrocodone, a short-acting opioid analgesic, combined with acetaminophen. The MTUS states that opioids are not recommended as first line therapy for neuropathic pain. Opioids are suggested for neuropathic pain that has not responded to first line recommendations including antidepressants and anticonvulsants. The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible dose should be prescribed to improve pain and function. Ongoing use of hydrocodone/acetaminophen requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. In this case, the medical records indicate that the injured worker has been on hydrocodone since at least June 2014. The

records do not document absence of aberrant pain behaviors or signs of abuse. The records do not document specific functional improvement or a pain assessment including the least reported pain over the period since the last assessment, average pain, and intensity of pain after taking the opioid, how long it takes for pain relief and how long pain relief lasts. Therefore, this request is not medically necessary.