

<b>Case Number:</b>	CM15-0175319		
<b>Date Assigned:</b>	09/16/2015	<b>Date of Injury:</b>	06/18/2013
<b>Decision Date:</b>	10/19/2015	<b>UR Denial Date:</b>	08/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/04/2015

### 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 49-year-old, male who sustained a work related injury on 6-18-13. The diagnoses have included bilateral lumbar radiculopathy, lumbar stenosis, lumbar herniated nucleus pulposus, lumbar myofascial pain and lumbar facet arthropathy. Treatments have included a lumbar epidural steroid injection (1-17-14), lumbar facet joint injection L5-S1 bilateral (7-11-14) (minimal benefit), use of a lumbar corset, left knee surgery, and oral medications. Current medications include Norco, Gabapentin and Omeprazole. In the progress notes dated 7-14-15, the injured worker reports severe, aching low back pain. He rates his pain level a 5 out of 10. He reports numbness through both legs. The numbness extends down into his toes. He reports severe right knee pain. Upon physical exam, he has a positive Bowstring sign, right greater than left. He has decreased sensation in the S1 dermatome, right greater than left. He has tenderness to touch over paraspinals in L3-S1, right greater than left. He has moderate limitation of bilateral lumbar extension and sidebending, right greater than left. He has positive lumbar facet loading on both sides, right greater than left. MRI of lumbar spine dated 6-20-13 reveals, "worsening degenerative changes at the level of L5-S1 with slight further increase in retrolisthesis. There is worsening disc disease and facet osteoarthritis with overall resultant mild central spinal stenosis, mild stenosis of the subarticular recesses and moderate stenosis of bilateral neural foramina all of which have increased in comparison to the prior study of 2008. The remainder of the levels is unchanged." EMG-NCV studies of bilateral lower extremities are abnormal. "The study showed evidence of an active mild left L4 lumbar radiculopathy with mild active denervation potentials present in one muscle of the L4 myotome."

He is currently not working. The treatment plan includes refills of medications, a prescription for Ketoprofen cream, a request for a bilateral transforaminal epidural steroid injection, physical therapy and a urine drug screen.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Ketoprofen 20% #1: 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 antiinflammatory 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 but rather the diagnosis of back 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.

### **1 Bilateral L5-S1 transforaminal epidural steroid injection: 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): Epidural steroid injections (ESIs).

**Decision rationale:** The California chronic pain medical treatment guidelines section on epidural steroid injections (ESI) states: Criteria for the use of Epidural steroid injections: Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007) 8) Current research does not support a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections. The patient has the documentation of back pain however previous ESI did not produce 50% reduction in pain lasting 6-8 weeks with decrease in medication usage. Therefore, the request is not medically necessary.