

<b>Case Number:</b>	CM15-0119033		
<b>Date Assigned:</b>	06/29/2015	<b>Date of Injury:</b>	11/25/2002
<b>Decision Date:</b>	09/21/2015	<b>UR Denial Date:</b>	05/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2015

### 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: Indiana

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 43-year-old male who sustained an industrial injury on 11/25/02. He reported low back and right shoulder pain after repetitive work activities. Initial diagnoses included lumbar strain/sprain. Treatments included radiographic imaging, MRI, anti-inflammatory/pain medication, lumbar spine and right shoulder steroid injections, and physical therapy. Current diagnoses include L4-S1 stenosis, postoperative radiculopathy, status post L4-5 total disc arthroplasty and L5-S1 fusion, left leg regional pain syndrome, and left S1 joint dysfunction. Treatments to date include surgical intervention, physical therapy, pain management, and psychotherapy. In a progress note dated 04/23/15 the injured worker reports pain in the bilateral shoulders, upper/lower extremities, and low back, rated as a 8.5 on a 10 point pain scale with medications. He has pain to the left ribs status post spinal cord stimulator implantation and cannot accurately determine the full benefit of the neurostimulator. Treatment recommendations include Percocet 10-325 #180, Biofreeze 4% gel x 3 refills, Lyrica 100 mg #60 x 3 refills, Zantac 300 mg x 3 refills, Oxycodone lowered to 20 mg #90, and Voltaren 1% gel x 3 refills. The injured worker is under total temporary disability. Date of Utilization Review: 05/21/15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Oxycodone HCL 20mg #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) and Pain, Opioids.

**Decision rationale:** Oxycodone is the generic version of Oxycotin, which is a pure opioid agonist. ODG does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request is not medically necessary.

**Percocet 10-325mg #180: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) and Pain, Opioids.

**Decision rationale:** ODG does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request is not medically necessary.

**Biofreeze 4% gel #1 with 3 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Procedure Summary.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 11-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) and Low Back, Topical Analgesics and Biofreeze.

**Decision rationale:** Biofreeze is a compound topical analgesic containing camphor and menthol. ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." ACOEM and MTUS are silent regarding the use of camphor. ODG states in the low back chapter regarding biofreeze, "recommended as an optional form of cryotherapy for acute pain. See also Cryotherapy, Cold/heat packs. Biofreeze is a nonprescription topical cooling agent with the active ingredient menthol that takes the place of ice packs. Whereas ice packs only work for a limited period of time, Biofreeze can last much longer before reapplication. This randomized controlled study designed to determine the pain-relieving effect of Biofreeze on acute low back pain concluded that significant pain reduction was found after each week of treatment in the experimental group. (Zhang, 2008)" Medical documents do not indicate that the Biofreeze is to be used for acute low back pain, which is indicated per ODG. As such, the request for Biofreeze gel is not medically necessary.

**Lyrica 100mg #60 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-epilepsy drugs / anti-convulsants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-epilepsy drugs Page(s): 16-17. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Anti-epilepsy drugs (AEDs) for pain.

**Decision rationale:** MTUS and ODG state that "Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and post-herpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Pregabalin listing for more information and references." MTUS additionally comments "Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants. Recommended for neuropathic pain (pain due to nerve damage). A 'good' response to the use of AEDs has been defined as a 50% reduction in pain and a 'moderate' response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the 'trigger' for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use." The patient appears to have established neuropathic pain for which Lyrica is an appropriate medication. The medical records provided do not detail any objective improvement over the last several months. Overall, pain improvement has not been documented or any functional benefits or side effects as required. Given the lack of subjective and objective improvement. As such, the request is not medically necessary.

**Zantac 300mg #60 with 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph last updated 01/21/2012.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; GI risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain; NSAIDs; GI risk and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: Uptodate.com, NSAIDs (including aspirin): Primary prevention of gastroduodenal toxicity.

**Decision rationale:** Ranitidine is an H2 antagonist used for the treatment of stomach ulcers and gastroesophageal reflux. MTUS states, "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). " And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." Uptodate states regarding H2 antagonist for GI prophylaxis, "Standard doses of H2 receptor antagonists were not effective for the prevention of NSAID-induced gastric ulcers in most reports, although they may prevent duodenal ulcers 33. Studies that detected a benefit on gastric ulcer prevention were short-term (12 to 24 weeks) and focused on endoscopic rather than clinical endpoints". The patient does not meet the age recommendations for increased GI risk. The medical documents provided establish the patient has experienced GI discomfort, but is nonspecific and does not indicate history of peptic ulcer, GI bleeding or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally, uptodate suggests that H2 antagonist at this dose is not useful for to prevent ulcers. As such, the request is not medically necessary.

**Voltaren gel 1% #1 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Procedure Summary.

**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; Compound creams.

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." MTUS specifically states for Voltaren Gel 1% (diclofenac) that is it "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." Medical records do not indicate that the patient is being

treated for osteoarthritis pain in the joints. As such, the request is not medically necessary.