

<b>Case Number:</b>	CM15-0047689		
<b>Date Assigned:</b>	03/19/2015	<b>Date of Injury:</b>	07/18/2006
<b>Decision Date:</b>	05/01/2015	<b>UR Denial Date:</b>	02/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/13/2015

### 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: 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 53-year-old male who sustained a work related injury on July 18, 2006, incurring lower back injuries. He was diagnosed with lumbar radiculopathy. Treatments included activity modification, Transcutaneous Electrical Nerve Stimulation (TENS), epidural steroid injections, lumbar fusion and physical therapy. Currently, in December 2014, the injured worker complained of low back pain with radiation to the right leg and depression. The treatment plan that was requested for authorization included prescriptions for Norco, Methoderm topical cream and Protonix.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain, opioids criteria for use Page(s): 78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78, 80.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids, including Norco. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an 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. There should be evidence of documentation of the "4 A's for Ongoing Monitoring". These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic back pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the "4 A's for Ongoing Monitoring". The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Norco is not medically necessary.

**Menthoderm topical cream:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-114.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics as a treatment modality. The MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. In this case, there is insufficient documentation as to the rationale for the use of the topical analgesic Mentoderm. This includes lack of clarity as to what type of pain Mentoderm is targeting. Further, if it is targeting neuropathic pain, then there is insufficient documentation that the patient has received an adequate trial of an antidepressant or anticonvulsant. For these reasons, Mentoderm is not medically necessary.

**Protonix 40mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & cardiovascular risk Page(s): 68 and 69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of a proton pump inhibitor (PPI), such as Protonix. Typically, PPIs are used as an adjunct to the use of an NSAID, when the NSAID is indicated and the patient is at risk for an adverse gastrointestinal event, such as an ulcer or GI bleeding. PPIs are recommended with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.) 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxen plus low-dose aspirin plus a PPI. In this case, the records indicate that the patient is at low risk for a significant GI event. There is no documentation to indicate that the patient has any of the significant risk factors that require the use of a PPI. For example, the patient is under 65 and has no documented history of GI ulcer or bleeding event. For these reasons, the use of Protonix is not medically necessary.