

<b>Case Number:</b>	CM15-0085626		
<b>Date Assigned:</b>	05/08/2015	<b>Date of Injury:</b>	02/22/2010
<b>Decision Date:</b>	06/12/2015	<b>UR Denial Date:</b>	05/04/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/05/2015

### 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 56-year-old male, who sustained an industrial injury on 2/22/2010. He reported injury to the neck, back and right shoulder. Diagnoses include left shoulder impingement syndrome, status post right shoulder surgery 7/14/14, cervical disc disease. Treatments to date include medication therapy and physical therapy. Currently, he complained of neck and back pain. On 4/21/15, the physical examination documented cervical and lumbar spine and muscle tenderness. The diagnoses included cervical disc disease, lumbar disc disease, impingement syndrome of the right shoulder and chronic pain, insomnia and depression. The plan of care included Protonix 20mg, Celebrex 200mg and Wellbutrin SR 150mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Protonix 20 mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), pain chapter, proton pump inhibitors.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID Page(s): 68-70.

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID therapy and proton pump inhibitors (PPI) states: Recommend 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 gastro duodenal 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 necessary. There is no documentation provided that places this patient at intermediate or high risk that would justify the use of a PPI. There is no mention of current gastrointestinal or cardiovascular disease. For these reasons, the criteria set forth above per the California MTUS for the use of this medication has not been met. Therefore, the request is not medically necessary.

**Generic Celebrex 200 mg #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID Page(s): 68-70.

**Decision rationale:** The California chronic pain medical treatment guidelines section on Celebrex states: Selective COX-2 NSAIDs: Celecoxib (Celebrex) is the only available COX-2 in the United States. No generic is available. Mechanism of Action: Inhibits prostaglandin synthesis by decreasing cyclooxygenase-2 (COX-2). At therapeutic concentrations, cyclooxygenase-1 (COX-1) is not inhibited. In animal models, it works as an anti-inflammatory, analgesic, and antipyretic. It does not have an anti-platelet effect and is not a substitute for aspirin for cardiac prophylaxis. Use: Relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, [and] ankylosing spondylitis. Side Effects: See NSAIDs, hypertension and renal function; & NSAIDs, GI Symptoms and Cardiovascular Risks. Cardiovascular: Hypertension (13%) CNS: headache (15.8%), dizziness (1% - 2%), insomnia (2.3%); GI: diarrhea (4% to 11%), dyspepsia (8.8% vs. 12.8% for ibuprofen and 6.2% for placebo), diarrhea (5.6%), abdominal pain (4.1% vs. 9% for ibuprofen and 2.8% for placebo), N/V (3.5%), gastroesophageal reflux (5%), flatulence (2.2%); Neuromuscular/ skeletal: arthralgia (7%), back pain (3%); Respiratory: upper respiratory tract infection (8%), cough (7%), sinusitis (5%), rhinitis (2%), pharyngitis (2%); Skin Rash (2%) discontinue if rash develops; Peripheral Edema (2.1%). Recommended Dose: 200 mg a day

(single dose or 100 mg twice a day). (Celebrex package insert) This patient is not at high risk for gastrointestinal events. The patient reportedly has hypertension but does not have major risk factors for cardiovascular disease per the California MTUS. The California MTUS recommends Naproxen as the first line choice in patients with mild to moderate risk factors for cardiovascular disease. There is no documented evidence of failure of Naproxen or gastrointestinal events, which would make the use of a COX-2 inhibitor necessary. Therefore, criteria for its use has not been met per the California MTUS guidelines and the request are not medically necessary.

**Wellbutrin SR 150 mg #60:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation PDR, wellbutrin.

**Decision rationale:** The ACOEM, ODG and California MTUS do not specifically address the requested medication for depression. The physician desk reference states the requested medication is a first line treatment option for depression with the FDA indication. The patient has depression and therefore the request is not medically necessary.