

<b>Case Number:</b>	CM14-0006083		
<b>Date Assigned:</b>	09/12/2014	<b>Date of Injury:</b>	10/29/2012
<b>Decision Date:</b>	10/21/2014	<b>UR Denial Date:</b>	01/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/13/2014

### 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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 female who was injured on 10/29/12 when a metal bar fell down and struck her left shoulder. Previous treatments include physical therapy, shoulder injections and pain medications with minimal help. Current diagnoses include left shoulder status post arthroscopy, subacromial decompression and AC joint resection and mild rotator cuff tendinitis of the left shoulder. Clinical note dated 10/30/13 indicated the injured worker complains of pain in her left shoulder but her range of motion is improving. She indicated she feels 60% improvement after surgery. She also complains of spasms intermittently in her left shoulder and gets functional improvement and pain relief with her medications. Physical examination revealed diffuse tenderness in her left shoulder, positive Neer's and Hawkin's tests, and positive greater tuberosity tenderness. Resisted abduction strength is 4/5, resisted external rotation strength is 4/5. Shoulder ranges of motion revealed forward flexion of 130 degrees, and pain with full forward flexion. Plan of management include a course of physical therapy, Cyclobenzaprine 7.5mg, Diclofenac XR 100mg, Omeprazole 20mg, Ondansetron 4mg, and Tramadol ER 150mg. MRI of the cervical spine on 11/14/13 revealed central disc protrusion that abuts the spinal cord producing canal narrowing in C3-4, C4-5, and C5-6. There is a central focal disc protrusion that abuts the thecal sac in C6-7; and straightening of the cervical lordosis which may be due to spasm. Clinical note dated 12/04/13 indicated the injured worker continues to have low back pain with neuropathic pain. The injured worker indicated she feels 70 percent improvement after her surgery. Physical examination revealed positive kyphotic deformity in the upper thoracic region. Lumbar spine range of motion has forward flexion of 60 degrees, with pain on full flexion. Examination of the left shoulder revealed diffuse tenderness on the left shoulder with well healed scars, and positive greater tuberosity tenderness. Resisted abduction strength is 4/5, resisted external rotation strength is 4/5. Shoulder ranges of motion revealed left

forward flexion of 130 degrees, and left abduction of 120 degrees. Medications include Diclofenac XR 100mg, Tramadol ER 150mg, and Omeprazole 20mg. The previous requests for Omeprazole 20mg, Ondansetron 4mg, Tramadol ER 150mg, NSAIDS #30, Cyclobenzaprine 7.5mg and Diclofenax XR 100mg were non-certified on 01/08/14.

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

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

#### **Omeprazole 20 mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Proton Pump Inhibitors.

**Decision rationale:** As noted in the Official Disability, proton pump inhibitors (PPIs) are indicated for patients at intermediate and high risk for gastrointestinal events with concurrent use of nonsteroidal anti-inflammatory drug use. Risk factors for gastrointestinal (GI) events include age greater than 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID (e.g., NSAID plus low dose ASA). There is no indication that the patient is at risk for gastrointestinal events requiring the use of proton pump inhibitors. Furthermore, long term PPI use (greater than one year) has been shown to increase the risk of hip fracture. As such, the request for omeprazole 20 mg is not medically necessary.

#### **Ondansetron 4 mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Antiemetics (for opioid nausea).

**Decision rationale:** As noted in the Pain chapter of the Official Disability Guidelines, antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Zofran is FDA approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA approved for postoperative use and acute gastroenteritis. There is no documentation of previous issues with nausea or an acute diagnosis of gastroenteritis. Additionally, if prescribed for postoperative prophylaxis, there is no indication that the patient has previously suffered from severe postoperative nausea and vomiting. Additionally, the medication should be prescribed once an issue with nausea and vomiting is identified, not on a prophylactic basis. As such, the request for Ondansetron 4 milligrams is not medically necessary.

**NSAIDs (non-steroidal anti-inflammatory drugs) #30 Gastritis Prophylaxis: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, specific drug list & adverse effects Page(s): 70.

**Decision rationale:** As noted in the Chronic Pain Medical Treatment Guidelines, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for acute exacerbations of chronic pain. NSAIDs are routinely associated with GERD and symptoms associated with gastritis frequently resulting in the need to obtain proton pump inhibitors or H-2 blocker treatment for gastritis prophylaxis. The request fails to provide the specific non steroidal anti-inflammatory drug to be requested. Additionally, it is unclear how a nonsteroidal anti-inflammatory drug will be utilized for gastritis prophylaxis. As such, the request for NSAIDs #30 gastritis prophylaxis is not medically necessary.

**Cyclobenzaprine 7.5 mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

**Decision rationale:** As noted in the Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine is recommended as a second line option for short term (less than two weeks) treatment of acute low back pain and for short term treatment of acute exacerbations in patients with chronic low back pain. Studies have shown that the efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. The request failed to provide the frequency, amount, and number of refills. As such, the request for Cyclobenzaprine 7.5mg is not medically necessary.

**Diclofenax XR 100 mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac (Voltaren) Page(s): 43.

**Decision rationale:** As noted in the Chronic Pain Medical Treatment Guidelines, diclofenac is not recommended as first line treatment due to increased risk profile. Post marketing surveillance has revealed that treatment with all oral and topical diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. The United States Federal Drug

Administration advised physicians to measure transaminases periodically in patients receiving long-term therapy with diclofenac and issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium. With the lack of data to support superiority of diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or nonpharmacological therapy should be considered. As such, the request for Diclofenax XR 100 milligrams is not medically necessary.