

<b>Case Number:</b>	CM15-0079094		
<b>Date Assigned:</b>	04/30/2015	<b>Date of Injury:</b>	08/14/2003
<b>Decision Date:</b>	06/01/2015	<b>UR Denial Date:</b>	03/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/24/2015

### 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: Massachusetts

Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 57 year old female, who sustained an industrial injury on August 14, 2013, incurring low back injuries. She was diagnosed with lumbar degenerative disc disease with radiculitis. Treatment included pain management. Currently, the injured worker complained of low back pain with radiation to the lower left extremity. The treatment plan that was requested for authorization included prescriptions for Fenoprofen Calcium (Nalfon), Omeprazole and Ondansetron.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fenoprofen Calcium (Nalfon) 400mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory drugs Page(s): 67, 68, 71.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID Page(s): 67, 73.

**Decision rationale:** According to the MTUS Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) Recommended with cautions below. Disease-State Warnings for all NSAIDs: All NSAIDs have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. Other disease-related concerns(non-boxed warnings): Hepatic: Use with caution in injured workers with moderate hepatic impairment and not recommended for injured workers with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of injured workers taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDs. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. Overall Dosing Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual injured worker treatment goals. According to the documents available for review, it appears that the injured worker is taking this medication for long-term therapy of a chronic condition. Given the increased risks associated with long-term use of this medication and no documented evidence that the lowest possible dose is being used for the shortest period of time, the requirements for treatment have not been met and medical necessity has not been established.

**Omeprazole 20mg #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines PPI Page(s): 68-69.

**Decision rationale:** The MTUS makes the following recommendations for the use of proton pump inhibitors. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the injured worker 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 Injured workers with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Injured workers 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 (200 g 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). Injured workers at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Injured workers 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 cardio protection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. Cardiovascular disease: A non-pharmacological choice should be the first option in injured workers with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. According to the records available for review the injured worker does not meet any of the guidelines required for the use of this medication therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**Ondansetron 8mg ODT #30:** 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, Antiemetics (for opioid nausea).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Zofran.

**Decision rationale:** Accordingly to the ODG, Zofran is a serotonin 5-HT<sub>3</sub> receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. According to the documents available for review, the injured worker does not have any of the FDA approved indications for the use of this medication. Therefore at this time the requirements for treatment have not been met and medical necessity has not been established.