

<b>Case Number:</b>	CM14-0186989		
<b>Date Assigned:</b>	11/17/2014	<b>Date of Injury:</b>	05/10/2013
<b>Decision Date:</b>	01/05/2015	<b>UR Denial Date:</b>	10/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/10/2014

### 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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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:

This is a 57 year old patient with date of injury of 5/10/2013. Medical records indicate the patient is undergoing treatment for right shoulder pain, cervical spine sprain/strain, bilateral shoulder bursitis, right rotator cuff tear, lumbar spine sprain/strain, and bilateral knee sprain/strain. Subjective complaints include constant right shoulder pain described as sharp and throbbing, aching neck pain with associated cracking, the pain radiates to the bilateral trapezius, difficulty sleeping, pinching pain in lumbar spine, bilateral knee pain, right greater than left with popping and cracking in both knees. Objective findings include limited right shoulder range of motion, healed incision. MRI of left knee without contrast showed mild effusion within the left knee joint and bursa, otherwise, normal magnetic resonance imaging study of the left knee. MRI of the right knee without contrast showed slight effusion within the right knee joint and bursa, otherwise normal. Treatment has consisted of Norco and Naproxen. The utilization review determination was rendered on 10/13/2014 recommending non-certification of Omeprazole 20mg #120, Ondansetron ODT 8mg #30, Tramadol ER 150mg #90 and Levofloxacin 750mg #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Omeprazole 20mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

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

**Decision rationale:** MTUS and ODG 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 Aspirin (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 (200 mg 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)." The medical documents provided do not establish the patient as having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. As such, the request for Omeprazole 20mg quantity #120 is not medically necessary.2. Ondansetron ODT 8mg #30 is not medically necessary and appropriate.The Claims Administrator based its decision on the Non-MTUS Official Disability Guidelines, Pain (Chronic). The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, NSAIDs, GI Symptoms, Opioids page 68-69, 74-96, and on the Non-MTUS Official Disability Guidelines (ODG) Chronic Pain, Antiemetics for Opioid Nausea..The Expert Reviewer's decision rationale:Ondansetron (Zofran) is an antiemetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin-norepinephrine reuptake inhibitors (SNRIs). ODG does not recommend use of antiemetic for "nausea and vomiting secondary to chronic opioid use". Additionally, "This drug is a serotonin 5-HT3 receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. MTUS is specific regarding the gastrointestinal symptoms related to NSAID usage. If criteria are met, the first line treatment is to discontinue usage of NSAID, switch NSAID, or consider usage of proton pump inhibitor. The medical documentation provided does not indicate subjective or objective complaints of nausea or vomiting. As such the request for Ondansetron ODT 8mg #30 is not medically indicated.

**Ondansetron ODT 8mg #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, Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms, Opioids Page(s): 68-69, 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Antiemetics for Opioid Nausea

**Decision rationale:** Ondansetron (Zofran) is an antiemetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin-norepinephrine reuptake inhibitors (SNRIs). ODG does not recommend use of antiemetic for

"nausea and vomiting secondary to chronic opioid use". Additionally, "This drug 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." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. MTUS is specific regarding the gastrointestinal symptoms related to NSAID usage. If criteria are met, the first line treatment is to discontinue usage of NSAID, switch NSAID, or consider usage of proton pump inhibitor. The medical documentation provided does not indicate subjective or objective complaints of nausea or vomiting. As such the request for Ondansetron ODT 8mg #30 is not medically indicated.

**Tramadol ER 150mg #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, (Tramadol (Ultram)) Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for Acute Pain (Analgesics), Tramadol (Ultram)

**Decision rationale:** Ultram is the brand name version of Tramadol, which is classified as central acting synthetic opioids. MTUS states regarding Tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/Acetaminophen."The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Tramadol prior to the initiation of this medication. The documentation provided shows that this patient has been utilizing Tramadol since January of 2014 with no documented functional improvement. As such, the request for Tramadol ER 150mg #90 is not medically necessary.

**Levofloxacin 750mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Clinical practice guidelines for Antimicrobial Prophylaxis in Surgery

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Up-to-date, Fluoroquinolones <http://www.uptodate.com/contents/fluoroquinolones>; Epocrates, Levaquin <https://online.epocrates.com/>.

**Decision rationale:** Fluoroquinolones are the only class of antimicrobial agents in clinical use that are direct inhibitors of bacterial DNA synthesis. They inhibit two bacterial enzymes, DNA gyrase and topoisomerase IV, which have essential and distinct roles in DNA replication. The fluoroquinolones are bactericidal. (See 'Mechanisms of action' above.) Fluoroquinolones, especially the newer agents, have a wide spectrum of activity that includes gram-negative bacilli, *Streptococcus pneumoniae* and other respiratory pathogens, other gram-positive cocci, and mycobacterial species. The specific antimicrobial spectrum varies with the different fluoroquinolones (table 1A and table 1B and table 2 and table 3). (See 'Spectrum of activity' above.) Fluoroquinolones can interact with a variety of other drugs. A common problem is that coadministration of fluoroquinolones with aluminum-, magnesium-, or, to a lesser extent, calcium-containing antacids leads to markedly reduced oral bioavailability of the quinolone, presumably because of the formation of cation-quinolone complexes, which are poorly absorbed. (See 'Drug interactions' above.) Prophylactic use of antimicrobials is not recommended for patients who are undergoing clean orthopedic procedures. Levofloxacin is not supported as a prophylactic medication post surgically. As such, the request for Levofloxacin 750mg #30 is not medically necessary.