

<b>Case Number:</b>	CM15-0077410		
<b>Date Assigned:</b>	04/28/2015	<b>Date of Injury:</b>	05/09/2006
<b>Decision Date:</b>	05/28/2015	<b>UR Denial Date:</b>	03/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/23/2015

### 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 55 year old female, who sustained an industrial injury on May 9, 2006. She reported falling down three steps with chairs falling onto her head, with pain in her back and into the right leg. The injured worker was diagnosed as having history of ACL reconstruction of the right knee, history of previous meniscectomy, left knee sprain, chronic low back pain, morbid obesity, history of diabetes, hypertension, history of reactive depression stable with Zoloft, dyspepsia from medications, and constipation. Treatment to date has included x-rays, MRIs, bracing, right knee arthroscopy, electromyography (EMG)/nerve conduction study (NCS), physical therapy, and medication. Currently, the injured worker complains of burning sensation at the left hip, low back, and left knee. The Primary Treating Physician's report dated February 25, 2015, noted the injured worker reported that with the help of medications, her pain was very well managed. The injured worker was noted to ambulate with a four point walker with wheels. Physical examination of the lumbosacral spine was noted to show severe tenderness throughout the lumbar paravertebrals, worse at L4-L5 and L5-S1, with restricted range of motion (ROM), and straight leg raise caused back pain bilaterally from a sitting position. Severe tenderness on the medical joint line bilaterally was noted on the examination of the bilateral knees, with swelling on the medial as well as the lateral joint lines. The treatment plan was noted to include starting Docuprene, refill of GLFCMK cream, Tramadol, Prilosec, Sertraline, and Dexilant, and awaiting authorization for physical therapy.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tramadol 50mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list, Criteria for use of Opioids, Weaning of medications Page(s): 93 to 94, 76-80, 124.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-97.

**Decision rationale:** According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: 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 injured worker's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the injured worker's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain injured workers on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the injured worker should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or injured worker treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) 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 does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the injured worker has returned to work, (b) the injured worker has improved functioning and pain. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and as required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established. The request IS NOT medically necessary.

**Omeprazole 20mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & 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 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). 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. The request IS NOT medically necessary.

**Dexilant 60mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & 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. The request IS NOT medically necessary.