

<b>Case Number:</b>	CM13-0007235		
<b>Date Assigned:</b>	12/11/2013	<b>Date of Injury:</b>	06/16/2011
<b>Decision Date:</b>	01/24/2014	<b>UR Denial Date:</b>	07/25/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/05/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine, and is licensed to practice in Washington, DC. 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 physician 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:

██████████ was a 58 year old female who was being seen for rotator cuff sprain and strain as well as lower back pain due to an industrial injury. The initial date of injury was June 16, 2011. UR request date was July 25, 2013 and it was for Omeprazole 20mg #60, Cyclobenzaprine 60, Norco 10/325mg 60. The relevant treating provider visit was on 07/16/13. The mechanism of injury was lifting recycling bags of paper and office equipment. She reportedly felt and heard a pop in the shoulder and then complained of worsening pain and stiffness. Radiographs showed no evidence of obvious bony abnormalities. An MRI on 07/06/11 showed a retracted rotator cuff tear. Her past medical history included hypertension and depression. Subsequently she was referred to an Orthopedic surgeon. However, she followed up with a chiropractor instead and failed to improve with multiple treatments. Subsequently she was referred to pain management and then to Orthopedic surgeon.. Lumbar spine MRI on Sept 18, 2012 showed L2-3, L3-4, L4-5 and L5-S1 broad based disc protrusion that abuts the thecal sac. Cervical spine MRI on Sept 18, 2012 showed C4-5 central focal disc protrusion, C6-7 broad based disc protrusion with spinal canal narrowing and foraminal narrowing. In addition, there was facet hypertrophy at L5-S1 producing spinal canal narrowing and bilateral neural foraminal narrowing. MRI of left shoulder on Sept 19, 2012 showed full thickness tear of the supraspinatus tendon with medial retraction, glenohumeral joint effusion and fluid in subacromial space, infraspinatus tendinosis, biceps tendinosis and subacromial cysts within the humeral head. MRI of right shoulder again showed full thickness tear of supraspinatus tendon and high grade partial thickness tear of infraspinatus tendon. In January 2013, she had arthroscopy of left shoulder and subsequent repair of left rotator cuff. In April 2013, the treating provider noted neck pain, headache, low back pain and bilateral shoulder pain. Ther

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Omeprazole 20mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), chronic pain, Proton pump inhibitors.

**Decision rationale:** According to MTUS guidelines, 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 gastroduodenal 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 (200 µg 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 absolutely necessary. According to Official disability guidelines, PPIs are recommended for patients at risk for gastrointestinal events. See NSAIDs, GI symptoms & cardiovascular risk. Prilosec® (omeprazole), Prevacid® (lansoprazole) and Nexium® (esomeprazole magnesium) are PPIs. Omeprazole provides a statistically significantly greater acid control than lansoprazole. (Miner, 2010) Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. For many people, Prilosec is more affordable than Nexium. Nexium is not available in a generic (as is Prilosec). Also, Prilosec is available as an over-the-counter product (Prilosec OTC®), while Nexium is not. (Donnellan, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Eff

**Cyclobenzaprine 7.5mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine.

**Decision rationale:** Cyclobenzaprine (Flexeril®<sup>®</sup>, Amrix®<sup>®</sup>, Fexmid®<sup>®</sup>, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) This medication is not recommended to be used for longer than 2-3 weeks. In this scenario, Flexeril was being used to manage chronic pain after an injury in 2011. There is no documentation of acute exacerbation of pain. The report suggests chronic pain without evidence of muscle spasms. Hence, Cyclobenzaprine is not recommended for this situation per above cited guidelines.

**Norco 10/325 #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Opioids.

**Decision rationale:** According to MTUS, for using Opioids, the following need to be done: 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 patient'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 patient's response to treatment. According to Official disability guidelines, Opioids are not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Recommended as a 2nd or 3rd line treatment option at doses ≤ 120 mg daily oral morphine equivalent dose (MED) as indicated below. Risk-benefit of use should be carefully weighed for substance abuse and overdose risks, including risk of death, and this information should be provided to the patient as part of informed decision-making. Extreme caution is required for any opioid use in patients with the following:

(1) Individuals with a high risk for misuse or diversion; (2) Individuals with evidence of substance abuse issues; (3) Individuals with a family history of substance abuse; (4) Individuals with underlying psychiatric disease. An accurate diagnosis should be established. At the minimum, screening for opioid risk and psychological distress inventories should occur before starting this class of drugs and a psychological evaluation is strongly recommended. Escalation of doses beyond 120 mg MED should be done with caution, and generally under the care of pain specialists. In certain cases, addiction specialists may need to evaluate patients, with the understanding that many patients who progress to chronic opioid therapy have underlying psychiatric disease and substance abuse issues. While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective in achieving the original goals of complete pain relief and functional restoration. For patients now on high opioid doses who are not benefiting from them, if taken off the medications many would experience severe withdrawal or have to take addiction treatment drugs for years. See Weaning of medications. To prevent new patients from getting caught in this cycle, ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases.-Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side eff