

Case Number:	CM14-0173088		
Date Assigned:	10/23/2014	Date of Injury:	12/05/2000
Decision Date:	11/25/2014	UR Denial Date:	09/22/2014
Priority:	Standard	Application Received:	10/20/2014

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 Occupational 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:

This case is a 52-year-old male with a date of injury on 12/5/2000. A review of the medical records indicates that the patient has been undergoing treatment for back, shoulder pain, and hypertension. Subjective complaints (6/26/2014) include low back pain of moderate intensity without radiation. Objective findings (6/26/2014) include decreased range of motion to right shoulder/lumbar spine, tenderness to lumbar spine and paraspinal muscles. Treatment has included lumbar surgery (date unknown), right shoulder surgery x 2 (2009), trigger point injection to lumbar spine, Protonix, Norco, Zipsor. A utilization review dated 9/22/2014 determined the following:- a request for Protonix suspension 40mg #30 with 1 refill was considered not medically necessary due to undocumented GI symptoms- Modified for generic Diclofenac x one month supply (original request Zipsor 25mg #90 with 1 refill) due to no documented need for liquid version and no documented improvement from medication.

IMR ISSUES, DECISIONS AND RATIONALES

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

Protonix suspension 40mg #30 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).

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: Protonix is the brand name version of Pantoprazole, which is a proton pump inhibitor. MTUS 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 ASA, Corticosteroids, and/or an Anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." In addition, "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 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)." ODG states, "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 Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)." The patient does not meet the age recommendations for increased GI risk. The medical documents do not establish GI discomfort, GI ulcer, or GI bleeding. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant. The patient is on an NSAID, but no GI symptoms are noted. Additionally per guidelines, Pantoprazole is considered second line therapy and the treating physician has not provided detailed documentation of a failed trial of Omeprazole and/or Lansoprazole. As such, the request for Protonix Suspension 40mg #30 with 1 refill is not medically necessary.

Zipsor 25mg #90 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Diclofenac

Decision rationale: Zipsor is the name brand version of Diclofenac, which is a NSAID. MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after Acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as Acetaminophen, Narcotic Analgesics, and Muscle Relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but

fewer effects than Muscle Relaxants and Narcotic Analgesics.4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The medical documents do not indicate that the patient is being treated for osteoarthritis. The treating physician does not document failure of primary (Tylenol) treatment. Importantly, ODG also states that Diclofenac is "Not recommended as first line due to increased risk profile . . . If using Diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events." As written, the patient would have this medication for 2 months without any interim medical monitoring or evaluation, which is excessive. Given the treatment history, 2 months of this medication does not appear to be the lowest dose and shortest duration possible. The original reviewer approved for one month of generic Diclofenac with 0 refills, which is appropriate. As such, the request for Zipsor 25mg #90 with 1 refill is not medically necessary.