

Case Number:	CM14-0180154		
Date Assigned:	11/04/2014	Date of Injury:	08/01/2012
Decision Date:	01/26/2015	UR Denial Date:	10/14/2014
Priority:	Standard	Application Received:	10/29/2014

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 Internal Medicine and is licensed to practice in District of Columbia. 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 40 year old patient who sustained injury on Aug 1 2012. He was diagnosed with chronic intractable lower back pain, degenerative disc disease of the lumbar spine, disc herniations of the lumbar spine, radiculitis of the bilateral lower extremities, neuropathic pain, greater trochanteric bursitis of the bilateral lower hips and depression. He was prescribed multiple medications: flexeril, diclofenac, omeprazole, tramadol, Zofran, Wellbutrin. He was also prescribed gabapentin and L5-S1 intralaminar epidural steroid injection for radicular symptoms.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro Diclofenac XR 100mg, #60: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 71.

Decision rationale: The patient had radicular signs and was being treated for pain with improvement. This medication would be indicated. Per MTUS, Diclofenac Sodium (Voltaren, Voltaren-XR) generic available: (Voltaren, diclofenac sodium enteric-coated tablet Package Insert), (Voltaren-XR, diclofenac sodium extended-release tablets Package Insert) Diclofenac

Potassium (Cataflam, generic available): (Cataflam, diclofenac potassium immediate-release tablets Package Insert) Different formulations of diclofenac are not necessarily bioequivalent. Dosing: Cataflam: Osteoarthritis: Adults: 50 mg PO (by mouth) 2--3 times daily. Dosages > 150 mg/day PO are not recommended. Pain: 50mg PO 3 times per day (max dose is 150mg/day). An initial dose of 100 mg PO followed by 50-mg doses may provide better relief. Voltaren: Osteoarthritis: 50 mg PO 2--3 times daily or 75 mg PO twice daily. Dosages > 150 mg/day PO are not recommended. In Ankylosing spondylitis: 25 mg PO 4 times a day with an extra 25-mg dose at bedtime if necessary. Voltaren-XR: 100 mg PO once therapy. Voltaren-XR should only be used as chronic maintenance therapy. The request is medically necessary.

Retro Omeprazole 20mg, #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: Per MTUS, Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors 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 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients 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. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine,2007). Cardiovascular disease: A non-pharmacological choice should be the first option in patients 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. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) Use with Aspirin for cardio protective effect: In terms of GI

protective effect: e GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007) In terms of the actual cardio protective effect of aspirin: Traditional NSAIDs (both ibuprofen and naproxen) appear to attenuate the anti-platelet effect of enteric-coated aspirin and should be taken 30 minutes after ASA or 8 hours before. (Antman, 2007) Cox-2 NSAIDs and diclofenac (a traditional NSAID) do not decrease anti-platelet effect. (Laine, 2007) Use of NSAIDs and SSRIs: The concurrent use of SSRIs and NSAIDs is associated with moderate excess relative risk of serious upper GI events when compared to NSAIDs alone. This risk was higher for non-selective NSAIDs when compared to Cox-2 selective agents (adjusted odds ratio of 1.77 and 1.33, respectively). (Helin-Salmivaara, 2007) Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI. The request is not medically necessary.

Retro Ondansetron 4mg, #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.rxlist.com/zofran-drug/indications-dosage.htm>

Decision rationale: MTUS and ACOEM do not address this medication so additional sources were sought. Per guidelines cited and given that this patient had no issues with nausea this medication would not be indicated. Zofran indications: 1. Prevention of nausea and vomiting associated with highly emetogenic cancer Chemotherapy, including cisplatin 50 mg/m². 2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. 3. Prevention of nausea and vomiting associated with radiotherapy in patients receiving total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen. 4. Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran Tablets, Zofran ODT Orally Disintegrating Tablets, and Zofran Oral Solution are recommended even where the incidence of postoperative nausea and/or vomiting is low. This request is not medically necessary.

Retro Cyclobenzaprine 7.5mg, #90: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41-42, 64-65.

