MAXIMUS Federal Services

Case Number:	CM14-0130492		
Date Assigned:	09/08/2014	Date of Injury:	10/23/2012
Decision Date:	10/30/2014	UR Denial Date:	07/30/2014
Priority:	Standard	Application Received:	08/15/2014

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 Family 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 37-year old man reported a low back injury due to lifting at work 10/23/14. Treatment to date has included medications, physical therapy, pool therapy, an epidural steroid injection, acupuncture, and TENS. He was judged not to be a surgical candidate. The available records contain an AME report that refers to notes from visits with the current primary treater which demonstrate that the patient was taking Relafen as early as 12/17/13. There are seven notes from the primary treater's office, all signed by mid-level providers, ranging in date from 1/21/14 through 7/7/14. The first four of these notes document that the patient is taking Relafen. These notes are signed by two different PAs. On 4/17/14 there is a note from a nurse practitioner which states that the patient does not really think Relafen is doing anything, and that it is causing GI upset. She recommends that he discontinue the Relafen and amitriptyline, take omeprazole on a temporary basis, and start a trial of gabapentin. There is a 5/9/14 note from a third PA which documents that the patient had had a pain flare-up. She adds Relafen back into the medication regimen with the rationale that the patient's pain is still a little high. She makes no reference to the previous provider's statements regarding lack of effectiveness and side effects of Relafen. There is a note dated 5/15/14 from the nurse practitioner which states that the patient is doing fine without the Relafen and amitriptyline, and that the gabapentin was helpful. The final note in the records, dated 7/7/14, is signed by one of the original two PAs. It makes no comment regarding whether or not the Relafen has been effective, and notes that the patient "gets some GI upset but omeprazole prevents that". Both Prilosec and Relafen were dispensed at the visit. None of the notes document any assessment of GI risk. None of them states exactly what the symptoms of "GI upset" are, and none documents an abdominal or rectal exam.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prilosec 20mg, #30 dispensed on 07/07/2014: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Edition, McGraw-Hill, 2006; Physician's Desk Reference, 68th Edition; www.rxlist.com; Official Disability Guidelines Drug Formulary, www.odg-twc.com/odgtwcformulary.htm; drugs.com; Epocrates Online, www.epocrates.com; Monthly Prescribing Reference, www.empr.com; Opioid Dose Calculator - AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov (as applicable)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS AND CARDIOVASCULAR RISK Page(s): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:UptoDate, an evidence-based online review service forclinicians, (www.uptodate.com) , Omeprazole: drug information

Decision rationale: Prilosec is brand-name Omeprazole, which is a proton pump inhibitor, or PPI.The first guideline cited above states that clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. They should determine if the patient is at risk for GI events. Risk factors include age over 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of aspirin, corticosteroids, or an anticoagulant; or high-dose or multiple NSAIDs, or an NSAID combined with aspirin.Patients with no GI risk factors and no cardiovascular disease may be prescribed a non-selective NSAID. Those at intermediate risk for GI disease should receive a non-selective NSAID plus a proton pump inhibitor (PPI) or misoprostol; or a Cox-2 selective NSAID. Patients at high GI risk should receive a Cox-2 selective NSAID and a PPI if an NSAID is absolutely necessary. This reference notes that long-term PPI use has been shown to increase the risk of hip fracture.The UptoDate reference cited above lists the indications for omeprazole as active duodenal ulcer, gastric ulcer, erosive esophagitis, helicobacter pylori eradication, pathological hypersecretory conditions (such as Zollinger-Ellison syndrome), frequent heartburn, GERD or other acid-related disorders, NSAID-induced ulcer treatment, NSAID-induced ulcer prophylaxis, and stress ulcer prophylaxis in ICU patients. The last three indications are off label. Risks of long-term (usually over one year) use include atrophic gastritis, increased incidence of gastric carcinoid tumors, clostridium difficile-associated diarrhea, increased incidence of osteoporosis-related fractures of the hip, spine, or wrist; hypomagnesemia and Vitamin B12 deficiency.The clinical findings in this case do not support the ongoing use of Prilosec. Two providers have stated that the patient is having "GI upset" while on Relafen, though one of them states it is prevented by Prilosec. If this patient is having GI upset while taking Relafen, Prilosec is obviously not preventing it. Since the records indicate that the patient does not find Relafen to be effective, the obvious action would be to discontinue both Relafen and Prilosec, since neither of them is producing the desired results. If "GI upset" refers to nausea or diarrhea, Prilosec is not even the indicated medication. Since none of the other indications listed above apply, the indication for use of Prilosec in this case would be NSAID-induced ulcer prophylaxis or NSAID-induced ulcer. The symptoms of these diagnoses would include abdominal pain, and possibly rectal bleeding or bloody vomiting, not "GI upset".

In addition, there is no documentation of any assessment for GI or cardiovascular risk factors. If he has cardiovascular risk factors, NSAID use is inappropriate, as is Prilosec if he is at low risk for GI disease. According to the evidence-based citations above, and the clinical findings in this case, Prilosec 20 mg #30, date of service 7/7/14, is not medically indicated. It is not medically necessary because it clearly did not stop the symptom for which it was started (GI upset), because there is no documented reason to continue it given that Relafen should also be stopped, and because no appropriate GI risk evaluation was performed which indicated it should have been started in the first place. Therefore, the request for Prilosec 20mg, #30 dispensed on 07/07/2014 is not medically necessary and appropriate.