

Case Number:	CM14-0207141		
Date Assigned:	12/19/2014	Date of Injury:	07/17/2008
Decision Date:	02/13/2015	UR Denial Date:	12/03/2014
Priority:	Standard	Application Received:	12/10/2014

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 Practice, 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:

Omeprazole is a proton pump inhibitor (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. Significant side effects include hepatic disease and hepatic failure. 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 documentation in this case does not support the provision of omeprazole to this patient. The provider's stated rationale, that it is being prescribed for GI protection with higher risk meds, does not make sense since the patient is not taking an NSAID or another medication that puts him at high risk for GI events. The records do not contain documentation of symptoms of gastritis or of an assessment of the

patient's risk factors for GI events. There is no documentation of any concern for another diagnosis that would require the use of a PPI. The patient has been taking omeprazole for at least 9 months, and probably for over a year. This long-term use puts him at increased risk for the side effects described above, some of which may be life threatening. Based on the clinical information provided for my review and the evidence-base citations above, omeprazole 20 mg #30 is not medically necessary. It is not medically necessary because the provider has not documented symptoms compatible with any condition that would require its use, because the provider has not documented any risk factors for GI events that would require its use, and because its long-term use puts the patient at unacceptable risk for serious side effects.

IMR ISSUES, DECISIONS AND RATIONALES

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

Home PT/INR monitoring: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Lab Tests Online

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: UptoDate, an online evidence-based review.

Decision rationale: According to the UptoDate reference cited above, the goal of a successful anticoagulation program is to ensure that the patient spends as much time as possible with an INR in the desired therapeutic range (usual target INR: 2.5, target range 2.0-3.0). The importance of strict INR control has been most effectively shown for anticoagulation in patients with nonvalvular atrial fibrillation. INRs of less than 2.0 have been associated with an increased risk of stroke, while INRs of over 3.0 have been associated with increased risk of bleeding. This article includes reviews of several large studies regarding anticoagulant management programs, and concludes that whenever possible, patients should be enrolled in either a self-management program or an anticoagulation clinic. These programs appear to offer better overall anticoagulation control and fewer anticoagulation-related side effects than standard management programs. The clinical documentation in this case supports the provision of home PT/INR monitoring to this patient. He has atrial fibrillation and coronary artery disease that has required several percutaneous angioplasties. He is at high risk for a thrombotic event, or for an embolic event. Although complete records are not available to me, it appears that his INRs are not in target range a significant portion of the time, and that a standard anticoagulation management program is not providing him with optimal control. Home INR monitoring (with appropriate training) appears to be entirely medically appropriate. Based on the evidence-based citation above and on the clinical documentation provided for my review, home PT/INR monitoring IS medically necessary. It is medically necessary because this patient is at high risk for thrombotic or embolic events, and because the available documentation suggests that he is out of target INR range a significant percentage of the time with conventional management, and because he would be likely to have better INR control with a home monitoring program.