

<b>Case Number:</b>	CM14-0201352		
<b>Date Assigned:</b>	12/11/2014	<b>Date of Injury:</b>	05/06/2013
<b>Decision Date:</b>	01/31/2015	<b>UR Denial Date:</b>	10/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/01/2014

### 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:

This 30-year old housekeeper reported injuries to both upper extremities, neck, back and hips after slipping and falling while cleaning a shower on 5/6/13. Treatment has included medications, physical therapy and chiropractic manipulation, acupuncture, and bilateral carpal tunnel releases. Current diagnoses include status post bilateral carpal tunnel release, cervical disc herniation with radiculopathy, cervicogenic headaches, left shoulder internal derangement, rule out disc herniation of the lumbar spine, anxiety and depression, and sexual dysfunction. She remains at total disability status according to her primary treater, a chiropractor, and apparently has not worked since her injury. She is also followed by an internist, who prescribes her medications and dispenses them from his office. The records contain several reports from the internist, ranging from 4/7/14 to 10/15/14. All of them contain extremely scanty documentation, mostly in checkbox form. Subjective complaints that are checked off include "GI check" and "taking meds as directed". There is also a handwritten abbreviation for headache. Gastrointestinal symptoms are never specifically documented. Objective findings include vital signs and eye findings. No abdominal exam is ever documented. Diagnoses include gastritis, insomnia and headache. The plan is always to "continue current meds". Ongoing medications are never specifically documented in the report, though new medications are written in by hand. There is no documentation that the patient is taking a non-steroidal anti-inflammatory drug (NSAID). The record contains the results of two drug screens performed 6/23/14 and 10/27/14. Both document the patient as taking hydrocodone, and both are negative for hydrocodone metabolites, and for all other opiates and opioids. This would suggest that the patient is not actually taking any opioids or opiates. A request for retroactive authorization of Zofran and Prilosec was submitted on 10/15/14. The internist's progress note from the same date does not document any rationale for dispensing either of these medications. The requests for Zofran and

Prilosec were non-approved in UR on 10/29/14 based on non-compliance with ODG guidelines for Zofran and with MTUS Chronic Pain guidelines for Prilosec.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Retrospective; Zofran every 8 hours #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter, ondansetron. UptoDate, an online, evidence-based review service for clinicians (www.uptodate.com), Ondansetron: Drug information.

**Decision rationale:** Zofran is brand name ondansetron, which is an anti-emetic used to treat nausea and vomiting. According to the UptoDate reference cited above, the medical indications for ondansetron (Zofran) include prevention of nausea and vomiting associated with chemotherapy. It may also be used for prevention of postoperative nausea and vomiting and for severe or refractory hyperemesis gravidarum (Canada only). Common side effects include headache, malaise/fatigue, and constipation. The ODG citation above states that ondansetron is not recommended for nausea and vomiting secondary to chronic opioid use. The clinical documentation in this case does not support the use of Zofran. The patient does not have any of the conditions for which it is indicated: she is not receiving chemotherapy, she is not in the immediate post-operative period, and she is not pregnant. The provider has documented no reason for the prescription of ondansetron. Although it is possible that it is opioid-associated nausea, the provider has not documented a complaint of nausea. It is not even clear that the patient is taking an opioid, given her repeated negative drug screens. In addition, the provider continues to document that the patient has headaches, which may actually be side effects from Zofran. Based on the evidence-based guideline cited above and on the clinical records provided for my review, Zofran every 8 hours #60 is not medically necessary. It is not medically necessary because there is no documented medical condition for which its use would be indicated, because in fact there is no documented reason of any sort for its use, and because it may be causing or contributing to the patient's ongoing complaint of headache.

**Retrospective; Prilosec 20 twice a day #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines PPI (Proton Pump Inhibitor).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular Page(s): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UptoDate, an evidence-based online review service for clinicians, (www.uptodate.com), Omeprazole: drug information.

**Decision rationale:** Prilosec is brand-name omeprazole, which 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. 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. It is impossible to guess from the available clinical records why omeprazole is being prescribed for this patient. Although there is a diagnosis of "gastritis", there is no documentation of what symptoms or findings led to the diagnosis, of whether or not it is ongoing, or whether or not it is felt to be secondary to NSAID use. There is no documentation that the patient is currently taking NSAIDs. There is no documentation of her risk for GI events. There is no documentation of any condition likely to require a PPI prescription, or of any symptoms suggestive of such a condition. It does appear likely that the patient has been taking Prilosec for at least a year, which would put her at risk for the side effects listed above, many of which could be life threatening. Based on the evidence-based references cited above and the available clinical information, Prilosec is not medically necessary because there is no documentation of any benefit to the patient that is likely to outweigh its risks.