

Case Number:	CM14-0199027		
Date Assigned:	12/09/2014	Date of Injury:	08/06/2007
Decision Date:	01/26/2015	UR Denial Date:	11/03/2014
Priority:	Standard	Application Received:	11/26/2014

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:

The patient is a 69 year-old man who was injured on 8/6/2007. The injury was primarily to his neck and back. He is requesting review of denial for Zofran 8mg #60 tablets that was prescribed on 9/18/2014. The medical records corroborate ongoing care for his injuries. These records include the Primary Treating Physician's Progress Reports. His chronic diagnoses include: Status Post Cervical Fusion; Cervical Discogenic Disease; Lumbar Discogenic Disease; Chronic Low Back Pain; and Lumbar Facet Syndrome. He has received the following medications from at least 6/19/2014: Norco, Prilosec, Ativan, Colace, Glucosamine, and Zofran. On 9/18/2014 he was seen in follow-up with his primary treating physician and was noted to have continued low back pain. He had received authorization for unspecified injections. There is no documentation of nausea, vomiting or adverse gastrointestinal side effects. In the Utilization Review process guidelines were not cited. The review indicated that "there is no documentation of nausea or vomiting in this claimant, thus Ondansetron cannot be recommended for certification. Additionally, it is not recommended for nausea and vomiting secondary to chronic opioid use."

IMR ISSUES, DECISIONS AND RATIONALES

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

Zofran 8 mg, sixty count, prescribed on September 18, 2014: 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 Opioids Page(s): 84. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain/Chronic, Anti-Emetics

Decision rationale: The CA/MTUS Chronic Pain Medical Treatment Guidelines do not comment on the use of anti-emetics such as Zofran for the treatment of nausea. However, the MTUS Guidelines do indicate that adverse side effects of chronic opioids include the following: epigastric pain, nausea, vomiting, constipation, dry mouth, dizziness, somnolence and headache. The Official Disability Guidelines do comment on the use of anti-emetics for nausea and vomiting secondary to chronic opioid use. The guidelines state the following: Anti-emetics (including Zofran) are "not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. Ondansetron (Zofran): This drug is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. In this case, there is no documentation on the rationale in support of the use of Zofran. There is no documentation, specifically in the 6/2014 or 9/2014 office visits indicating that the patient was experiencing nausea or vomiting or other gastrointestinal symptoms. Given the lack of documentation as to the medical indications for the use of Zofran and the lack of support of the Official Disability Guidelines, Zofran is not considered as medically necessary.