

<b>Case Number:</b>	CM14-0164678		
<b>Date Assigned:</b>	10/09/2014	<b>Date of Injury:</b>	08/26/2013
<b>Decision Date:</b>	11/19/2014	<b>UR Denial Date:</b>	09/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/06/2014

### 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 Occupational Medicine and is licensed to practice in Colorado. 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 injured worker is a 38-year-old Plumber Apprentice who developed low back pain at work on August 26, 2013 when lifting a large water jug. As of March 11, 2014, the injured worker complained of intermittent pain in the low back radiating to right lower extremity with some associated tingling and numbness, as well as headaches, as well as cervical spine pain. The worker was not using medications at this point in time. A diagnosis of lumbar discopathy was provided. On March 11, 2014 there is prescription information provided indicating the purpose for the Odansetron medication include as-needed for upset stomach/cramping, pain/nausea, no more than twice a day. The indications for Prilosec/omeprazole include as-needed for upset stomach. An MRI scan of the lumbar spine was obtained on July 3, 2014 which showed a disc protrusion at L5-S1 on the right without displacement of the nerve roots. There were shallow disc protrusions at L3-4 and L4-5. On August 15, 2014 the worker's of symptoms are documented as including constant pain in the low back with radiation into the lower extremities. On examination there was muscle tenderness in the paravertebral musculature with a positive nerve root test and restricted range of motion. There is tingling and numbness in the anterolateral thigh, knee, and medial left foot in the L4 dermatome. Motor strength was normal. Treatment plan included physical therapy, refill of medications and referral to pain management and neurology. Diagnosis was lumbago. Medications included omeprazole 20 mg p.o. q. 12 hours and Odansetron 8 mg oral disintegrating tablets (ODT) b.i.d. p.r.n. A request for omeprazole was indicated for gastrointestinal symptoms. The request for Odansetron is for nausea associated with headaches present with chronic cervical spine pain.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Omeprazole 20 MG 1 by mouth 12 Hours as needed #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 67-68.

**Decision rationale:** The MTUS states that omeprazole is used for patients at intermediate risk for gastrointestinal events and no cardiovascular disease during NSAID use and that long-term omeprazole use (> 1 year) has been shown to increase the risk of hip fracture. Omeprazole is used for treatment of dyspepsia secondary to NSAID therapy and to treat symptomatic Gastroesophageal Reflux Disease. In this case, although the request for omeprazole was listed for gastrointestinal symptoms there are no documented symptoms of gastroesophageal reflux disease, gastritis, or dyspepsia secondary to NSAID therapy. In terms of prevention, the worker's risk profile appears to be low. According to the MTUS, those at risk for gastrointestinal events are as follows: (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). Therefore, the request for Omeprazole is not medically necessary and appropriate.

**Ondansetron 8 MG ODT 1 as needed No More Than 2 Per Day #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Aetna Non-Medicare Prescription Drug Plan, Subject: Antiemetics <http://www.aetna.com/products/rxnonmedicare/data/2014/GI/antiemetics.html> and, the Aetna Clinical Policy Bulletin: Antiemetic Injection Therapy [http://www.aetna.com/cpb/medical/data/700\\_799/0724.html](http://www.aetna.com/cpb/medical/data/700_799/0724.html)

**Decision rationale:** On July 21, 2010 the US Food and Drug Administration (FDA) approved an oral soluble film formulation of ondansetron (Zofran) for the prevention of nausea and vomiting associated with highly and moderately emetogenic chemotherapy, radiotherapy, and surgery. Current indications for Zofran provided by the FDA include the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy and prevention of postoperative nausea and/or vomiting. There are no current FDA listed indications for ondansetron (Zofran) regarding nausea associated with cervical spine pain or, for opioid use. The indications for intravenous Zofran according to the Aetna clinical policy bulletin, anti-emetic injection therapy, include prevention of acute and delayed nausea and/or vomiting associated with initial and repeat courses of moderately and highly immunogenic cancer

chemotherapy including high-dose cisplatin, and a treatment of chemotherapy-induced nausea and/or vomiting of low or minimally immunogenic cancer chemotherapy in persons who have an adequate response or contraindication to oral agents including granisetron (Kytrel) or ondansetron (Zofran) at the FDA recommended dose. The indications for Zofran ODT according to the Aetna clinical policy bulletin for non-Medicare prescription drugs, subject: Antiemetics, are for a documented diagnosis of cancer and chemotherapy or radiation therapy or hyperemesis gravidarum. In this case, the request for Ondansetron appears to be for nausea associated with headaches present with chronic cervical spine pain and/or for nausea associated with opioid use. The medical records do not specifically document that the injured worker is experiencing significant nausea whether from neck pain or from opioid use. The medical records do not document other potential indications for the use of this medication such as post-surgical nausea or chemotherapy-associated nausea. With these factors for consideration, the request for Ondansetron ODT is not medically necessary and appropriate.