

<b>Case Number:</b>	CM15-0210413		
<b>Date Assigned:</b>	10/29/2015	<b>Date of Injury:</b>	09/05/2001
<b>Decision Date:</b>	12/10/2015	<b>UR Denial Date:</b>	10/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/26/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following  
 credentials: State(s) of Licensure: California  
 Certification(s)/Specialty: Family Practice

### 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 72-year-old female who sustained an industrial injury on 09-05-2001. A review of the medical records indicated that the injured worker is undergoing treatment for post-lumbar laminectomy syndrome, lumbosacral neuritis, drug dependence (status post detox), gastroesophageal reflux disorder (GERD) and cervical chronic pain. The injured worker is status post L3-S1 interbody fusion in 2001, revision of the lumbar spine in 2003, anterior exploration of L3-S1 fusion and repair in 2007, removal of hardware from the lumbar spine on 06-03-2015, revision of lumbar spine fusion in 06-10-2015, C5-C7 fusion in 2002, spinal cord stimulator (SCS) trial in 05-2010, spinal cord stimulator (SCS) implant in 07-2010, spinal cord stimulator (SCS) explant in 03-2011 and esophageal surgery secondary to diaphragm tear in 09-2013. According to the treating physician's progress report on 10-07-2015, the injured worker continues to experience lower back pain associated with numbness and weakness rated as 9 out of 10 and neck pain as 7 out of 10 on the pain scale. The injured worker reported pain medication lasts for approximately 3 hours. There was no change in objective findings from the prior office visits. Prior treatments have included diagnostic testing, multiple surgical interventions, physical therapy, transcutaneous electrical nerve stimulation (TENS) unit, massage therapy, facet joint injections, epidural steroid injection, spinal cord stimulator (SCS) trial, implant and explant, lumbar back brace, heat and ice therapy, acupuncture therapy, lumbar nerve root block and medications. Current medications were listed as Norco 10mg-325mg, Lyrica, Lidoderm, Famotidine, Nexium, Ondansetron (started 08-2015) and Miralax. Treatment plan consists of increasing Norco from 4 times a day to 6 times a day, continuing ice and moist heat and the current request for Ondansetron 4mg disintegrating tab #27. On 10-15-2015, the

Utilization Review determined the request for Ondansetron 4mg disintegrating tab #27 was not medically necessary.

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

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

#### **Ondansetron 4mg disintegrating tab #27: 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 (Chronic, updated 10/9/15), Antiemetics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: PainSection: Antiemetics for Opioid-Nausea.

**Decision rationale:** The Official Disability Guidelines comment on the use of antiemetics, including Ondansetron, as a treatment modality. Antiemetics 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-HT<sub>3</sub> 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, the records do not describe the rationale for the use of ondansetron. There is no evidence that an evaluation has been done to assess the patient for the underlying cause of nausea. Finally, the above-cited guidelines do not recommend the use of ondansetron for opioid-induced nausea. For these reasons, ondansetron is not medically necessary.