

<b>Case Number:</b>	CM13-0046839		
<b>Date Assigned:</b>	12/27/2013	<b>Date of Injury:</b>	01/24/1991
<b>Decision Date:</b>	06/19/2014	<b>UR Denial Date:</b>	11/07/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/12/2013

### 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 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 claimant was injured on 01/14/91 when he was trying to restrain a seizure patient. The patient sustained 3 HNPs and has also needed extensive dental work and has seen specialists for that treatment. There was an office visit with [REDACTED] on 10/24/12. There were complaints of consistent worsening low back pain due to repetitive falls; and minimal relief of pain meds as he was awaiting his dental work. It was noted that the patient had an upcoming spinal surgery. The patient had severe paralumbar and thoracic myospasm. He was ambulating with a cane. He was not somnolent. Diagnoses included neuralgia/neuritis/radiculitis and common migraine with lumbar disc disease with myelopathy, depression, and anxiety and the treatment plan include Toradol, methadone, Cymbalta, Zantac, osteopathic treatment, and urine drug screen. He was permanent and stationary. There were some inconsistent results of urine drug screen that including the presence of fentanyl and norfentanyl (later determined to be appropriate due to the use of fentanyl in his intrathecal pump). The patient is status post L3-S1 fusion and lumbar neuritis with progression of deterioration of the L2-L3 level and scoliosis. The patient was noted to have major depression, was falling daily, and pain medications gave him 20% relief of pain. He has required ongoing use of multiple medications. His pain is generally poorly controlled. The patient reportedly tried to limit his narcotic use, but has struggled for pain control. There was bony union of the interbody graft. The patient had severe pain and has been severely functionally limited despite his use of multiple medications. [REDACTED] had recommended additional surgery on his back, but he has declined to schedule it. On 01/04/13, [REDACTED] wrote a letter indicating that he should have ondansetron for his significant nausea due to his pain and his use of narcotics. There is continued neck and back pain radiating into both legs; and significant psychological findings. On 03/14/13, [REDACTED] stated that his pain was getting worse and he really needed to see the surgeon. [REDACTED] stated on 03/29/13, that he was taking

Ondansetron, which he had started needing after beginning the intrathecal medication. The patient had some fairly severe tardive Dyskinesia with other antiemetic and only Zofran seemed to be effective for him. There was a need for shoulder surgery according to [REDACTED] on 07/24/13. On 09/15/13, he was evaluated for ongoing low back pain, neck and upper back pain, bilateral leg pain, migraine headaches, and also developed a swollen left leg. There was a concern for DVT.

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

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

#### **ZOFRAN 4MG #120 WITH 1 REFILL: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Formulary

**Decision rationale:** The Official Disability Guidelines (ODG) Formulary states Zofran is "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 antiemetic 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. (Moore 2005).... 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." The ODG do not support the use of this medication in the circumstances described in these records. In this case, there is no documentation of significant nausea or vomiting in the file and the severity of the claimant's complaints is unclear. The provider's office notes do not mention these types of symptoms though [REDACTED] does report them in his appeal letter. The pattern of symptoms and use of this medication, including the degree and duration of relief of these symptoms have not been described. The medical necessity of the ongoing use of this medication has not been clearly demonstrated. Therefore, the request for Zofran 4mg # 120 with 1 refill is not medically necessary and appropriate.