

<b>Case Number:</b>	CM15-0107073		
<b>Date Assigned:</b>	06/11/2015	<b>Date of Injury:</b>	05/18/2010
<b>Decision Date:</b>	07/16/2015	<b>UR Denial Date:</b>	05/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/03/2015

### 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: Texas, New York, California  
 Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 applicant is a represented 44-year-old [REDACTED] beneficiary who has filed a claim for chronic low back, neck, shoulder, and hand pain reportedly associated with an industrial injury of May 18, 2010. In a Utilization Review report dated May 11, 2015, the claims administrator failed to approve a request for Zofran. The claims administrator referenced an April 6, 2015 office visit in its determination. On said April 6, 2015 progress note, the applicant reported ongoing complaints of neck, shoulder, and low back pain. The applicant did report issues with episodic nausea and/or vomiting apparently generated by Duragesic usage. Duragesic, Protonix, Remeron, and Zofran were all renewed, as were the applicant's permanent work restrictions. The attending provider suggested that the applicant was not working with said limitations in place, although this was not explicitly stated. On June 2, 2015, the attending provider again noted that he had chosen to continue Zofran for Duragesic induced nausea.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ondansetron-Zofran 4 mg #10:** 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:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management Page(s): 7-8. Decision based on Non-MTUS Citation ODG Integrated Treatment/ Disability Duration Guidelines Pain (Chronic), Antiemetics (for opioid nausea) and Other Medical Treatment Guidelines <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm271924.htm> U.S. Food and Drug Administration Ondansetron (marketed as Zofran) Information Ondansetron is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery. It is in a class of medications called 5-HT<sub>3</sub> receptor antagonists and works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.

**Decision rationale:** Pages 7 and 8 of the MTUS Chronic Pain Medical Treatment Guidelines stipulate that an attending provider using a drug for non-FDA labeled purposes has the responsibility to be well informed regarding usage as mentioned, furthermore, furnish compelling evidence to support such usage. The Food and Drug Administration (FDA) notes that Ondansetron (Zofran) is indicated in the treatment of nausea and vomiting caused by cancer chemotherapy, radiation therapy, and/or surgery. Usage for Zofran for Duragesic-induced nausea, thus, amounted to a non-FDA labeled role for the same. The attending provider failed to furnish a compelling applicant-specific rationale or medical evidence so as to support such usage in the face of the unfavorable FDA position on the same. In a similar vein, ODG, Chronic Pain chapter Antiemetics topic notes that antiemetics such as promethazine (Phenergan) are not recommended for nausea and vomiting secondary to chronic opioid use, as was present here. Therefore, the request is not medically necessary.