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| <b>Case Number:</b>   | CM14-0015617 |                              |            |
| <b>Date Assigned:</b> | 02/28/2014   | <b>Date of Injury:</b>       | 05/08/2013 |
| <b>Decision Date:</b> | 08/04/2014   | <b>UR Denial Date:</b>       | 01/13/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 02/07/2014 |

### 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 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 44-year-old male who has submitted a claim for intermittent low back pain, left knee possible patellar tendinitis, associated with an industrial injury date of May 8, 2013. Medical records from 2013 through 2014 were reviewed. The latest progress report, dated 01/08/2014, showed left knee pain and low back pain. Physical examination revealed tenderness from the mid to distal lumbar segments. There was pain with terminal motion. Seated nerve root test was positive. The left knee revealed tenderness at the left knee joint line. There was positive patellar compression test. There was pain with terminal flexion. The patient had a history of right knee arthroscopy from non-industrial injury. Treatment to date has included medications such as Ondansetron since June 2013. Utilization review from 01/13/2014 denied the request for the purchase of Ondansetron ODT tablets 8mg #30x2 QTY:60 because it was prescribed for nausea as a side effect to Cyclobenzaprine. Prophylaxis of nausea secondary to medication was not an indication for Ondansetron per FDA. The patient has not had recent surgery or radio- or chemotherapy.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**ONDANSETRON ODT TABLETS 8MG, #30 X 2 QTY: 60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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: U.S. Food and Drug Administration, Drug Safety Information, Ondansetron.

**Decision rationale:** The California MTUS does not address Ondansetron specifically. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the U.S. Food and Drug Administration, Drug Safety Information was used instead. The FDA states that ondansetron is indicated for prevention of nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery. In this case, Ondansetron was prescribed since June 2013 for nausea associated with intake of Cyclobenzaprine. However, this is not labeled, FDA-supported use of the medication. In addition, the recent clinical evaluation did not provide evidence for any subjective complaints of nausea. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for Ondansetron Odt Tabs 8 MG 30X2 #60 is not medically necessary.