

<b>Case Number:</b>	CM15-0081511		
<b>Date Assigned:</b>	05/04/2015	<b>Date of Injury:</b>	03/07/2007
<b>Decision Date:</b>	06/30/2015	<b>UR Denial Date:</b>	03/31/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/28/2015

### 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, 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:

This is a 44-year-old female patient, who sustained an industrial injury on October 7, 2008. She was diagnosed lumbar degenerative disc disease with lumbar radiculopathy and left shoulder impingement. A recent detailed clinical evaluation note is not specified in the records provided. Per the note dated 9/15/14, she had no change in abdominal pain, constipation and acid reflux. The physical examination of the abdomen revealed soft and normoactive bowel sound. The medications list includes amitiza, probiotics, zofran, colace and lansoprazole. Treatment included physical therapy, pain medications, steroid injections and surgical interventions. Patient had urine drug screen in 9/2014. The treatment plan that was requested for authorization included prescriptions for Colace, Probiotics, Zofran and a urine toxicology screen.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Colace 250mg #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 Official Disability Guidelines (ODG) Chapter: Pain (updated 06/15/15) Opioid-induced constipation treatment and Other Medical Treatment Guidelines Thompson Micromedex FDA labeled indication for Docusate sodium.

**Decision rationale:** Request- Colace 250mg #60. Colace contains Docusate sodium. According to the Thompson Micromedex, FDA labeled indication for Colace includes "constipation care." The medications list includes amitiza, probiotics, zofran, colace and lansoprazole. Per the records provided patient had constipation and was certified for amitiza. A rationale for the need of additional medications for constipation is not specified in the records provided. A detailed history regarding constipation is not specified in the records provided. A recent detailed clinical evaluation note is not specified in the records provided. Other measures for treatment of constipation are not specified in the records provided. Colace 250mg #60 is not medically necessary for this patient.

**Urine toxicology screen:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Urine Drug Testing.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 06/15/15) Opioids, tools for risk stratification & monitoring Urine drug testing (UDT).

**Decision rationale:** Request-Urine toxicology screen. Per the CA MTUS guideline cited above, drug testing is "Recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs." Per the records provided the medications list includes amitiza, probiotics, zofran, colace and lansoprazole. Patient had urine drug screen in 9/2014. This urine drug screen report is not specified in the records provided. Any evidence that the patient had a history of taking illegal drugs or potent high dose opioids is not specified in the records provided. Per the cited guidelines " Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results." History of aberrant drug behavior is not specified in the records provided. The rationale for a repeat urine drug screen, is not specified in the records provided. Urine toxicology screen is not medically necessary for this patient at this juncture.

**Probiotics #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 PubMed Probiotics: do they help to control intestinal

inflammation Bhm SK, Kruis W Ann N Y Acad Sci. 2006;1072:339. PubMed: The role of antibiotic and probiotic therapies in current and future management of inflammatory bowel disease. Ewaschuk JB, Tejpar QZ, Soo I, Madsen K, Fedorak RN Curr Gastroenterol Rep. 2006;8(6):486. PubMed: Use of probiotics in the treatment of inflammatory bowel disease. Hart AL, Stagg AJ, Kamm MA J Clin Gastroenterol. 2003; 36(2): 111. PubMed Probiotic lactobacilli: a new perspective for the treatment of inflammatory bowel disease. Famularo G, Mosca L, Minisola G, Trinchieri V, De Simone C Curr Pharm Des. 003; 9(24): 1973.

**Decision rationale:** Request-Probiotics #60. As per cited references the Probiotics are useful in antibiotic associated diarrhea, inflammatory bowel disease, especially ulcerative colitis, probiotics offer a safe alternative to current therapy and helpful in the prevention and treatment of acute diarrhea in adults and children and have some effects on the course of inflammatory bowel diseases (IBD). A recent detailed clinical evaluation note is not specified in the records provided. Any evidence of acute diarrhea and inflammatory bowel diseases (IBD)-ulcerative colitis was not specified in the records provided. The records provided did not specify any current use of antibiotics. Probiotics #60 is not medically necessary for this patient at this time.

**Zofran 4mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 06/15/15) Ondansetron (Zofran) Antiemetics (for opioid nausea).

**Decision rationale:** Request-Zofran 4mg #60. Ondansetron is 5-HT<sub>3</sub> receptor antagonist which acts as anti-emetic drug. CA MTUS/ACOEM does not address this request. Therefore, ODG was used. According to the ODG guidelines, "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." A detailed history related to nausea or vomiting is not specified in the records provided. Any evidence of chemotherapy and radiation treatment is not specified in the records provided. Evidence of recent surgery is not specified in the records provided. A recent detailed gastrointestinal examination is not specified in the records provided. Zofran 4mg #60 is not medically necessary for this patient.