

<b>Case Number:</b>	CM14-0061666		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	06/20/2006
<b>Decision Date:</b>	08/08/2014	<b>UR Denial Date:</b>	04/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/02/2014

### 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 Internal Medicine and is licensed to practice in New York. 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 is a 64 year old female clerk with [REDACTED] who sustained an industrial injury when her foot got caught in cords around her desk causing her to fall on 06/20/2006. Her diagnoses include neck pain, low back pain, left lower extremity, left hip, depression, upper and lower GI issues. On exam there are no abnormal abdominal findings. She is maintained on Prilosec therapy. The treating provider has requested Probiotics, Gaviscon, Prilosec 20mg #45, and Sentra AM/PM #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Pro-Biotics:** 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: Medscape Internal Medicine 2013- Probiotics.

**Decision rationale:** Probiotics are live nonpathogenic microorganisms administered to improve microbial balance, particularly in the gastrointestinal tract. They consist of Saccharomyces boulardii yeast or lactic acid bacteria, such as Lactobacillus and Bifidobacterium species, and are

regulated as dietary supplements and foods. Probiotics exert their beneficial effects through various mechanisms, including lowering intestinal pH, decreasing colonization and invasion by pathogenic organisms, and modifying the host immune response. Probiotics are generally considered safe and well tolerated, with bloating and flatulence occurring most frequently. They should be used cautiously in patients who are critically ill or severely immunocompromised or those with central venous catheters since systemic infections may rarely occur. Bacteria-derived probiotics should be separated from antibiotics by at least two hours. Probiotics have demonstrated efficacy in preventing and treating various medical conditions, particularly those involving the gastrointestinal tract. Data supporting their role in other conditions are often conflicting. There is no specific indication for the use of probiotics in relation to the claimant's industrial injury. Medical necessity for the requested item has not been established. The requested item is not medically necessary.

**Gaviscon #1:** Upheld

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

**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: Medscape Internal Medicine 2013- Antacid therapy.

**Decision rationale:** Antacids such as Gaviscon, are taken by mouth to relieve heartburn the major symptom of gastroesophageal reflux disease, or acid indigestion. Treatment with antacids alone is symptomatic and only justified for minor symptoms. The treatment of ulcers resulting from excessive acidity may require H<sub>2</sub>-receptor antagonists or proton-pump inhibitors, and eradication of *H. pylori*. There is no specific documentation indicating that the claimant's gastric reflux is related to her industrial injury. In addition there is no specific indication for the treatment of Gaviscon with a proton pump inhibitor such as Prilosec. Based on the available information provided for review, the medical necessity for Gaviscon has not been established. The requested medication is not medically necessary.

**Prilosec 20 mg #45:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms, and cardiovascular risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**Decision rationale:** Per California MTUS 2009 proton pump inhibitors are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. There is no documentation indicating the patient has any symptoms or GI risk factors. GI risk factors include: age >65, history of peptic ulcer, GI bleeding, or perforation; concurrent use of aspirin, corticosteroids, and/or anticoagulants or high dose/multiple NSAID. Per the documentaiton the claimant is not on any NSAID therapy. There is no specific documentaiton indicating that the claimant's gastric reflux is related to her industrial injury. Her complaints of bright red blood per

rectum were evaluated with a colonoscopy which demonstrated only internal hemorrhoids. There is no report of the upper endoscopy results. Based on the available information provided for review, the medical necessity for Prilosec has not been established. The requested medication is not medically necessary.

**Sentra AM #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-Pain(Chronic)(updated 10/14/2013) Medical Foods.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation X Other Medical Treatment Guideline or Medical Evidence: Sentra AM /PM product Information.

**Decision rationale:** There is no documentation provided necessitating the use of Sentra AM/PM. The product is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, neurotoxicity-induced fatigue syndrome and cognitive impairment involving arousal, alertness, and memory. It is a medical food that must be used under the supervision of a physician. There is no documentation provided indicating the patient has any of the above conditions and that any food supplement is required to provide a balance of this product's specific components to meet any increased requirements of muscle dysfunction, sleep disturbances, cognitive impairment, and chronic stress. Medical necessity for the requested treatment has not been established. The requested treatment is not medically necessary.

**Sentra PM #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-Pain(Chronic)(updated 10/14/2013) Medical Foods.

**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: Sentra AM /PM product Information.

**Decision rationale:** There is no documentation provided necessitating the use of Sentra AM/PM. The product is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, neurotoxicity-induced fatigue syndrome and cognitive impairment involving arousal, alertness, and memory. It is a medical food that must be used under the supervision of a physician. There is no documentation provided indicating the patient has any of the above conditions and that any food supplement is required to provide a balance of this product's specific components to meet any increased requirements of muscle dysfunction, sleep disturbances, cognitive impairment, and chronic stress. Medical necessity for the requested treatment has not been established. The requested treatment is not medically necessary.

