

<b>Case Number:</b>	CM15-0071017		
<b>Date Assigned:</b>	04/21/2015	<b>Date of Injury:</b>	04/03/2008
<b>Decision Date:</b>	05/20/2015	<b>UR Denial Date:</b>	03/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/14/2015

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 injured worker is a 62 year old female, who sustained an industrial/work injury on 4/3/08. She reported initial complaints of pain in hands spine, neck, and upper and lower back. The injured worker was diagnosed as having gastric esophageal reflux disease, diarrhea, abdominal pain, and unspecified sleep disturbance. Treatment to date has included medication, diagnostics, orthopedic management, and psychiatric evaluation. Abdominal sonogram results were reported on 10/13/11 that was negative. Echocardiogram on 10/13/11 was negative. Upper endoscopy on 6/21/12 was negative. Electromyography and nerve conduction velocity test (EMG/NCV) on 1/23/13 noted changes of denervation and re-innervation in the ulnar territory bilaterally. X-Rays results were reported on 1/23/13 that demonstrated lumbar and cervical degenerative spondylosis. Currently, the injured worker complains of acid reflux, occasional nausea, constipation, and diarrhea. Per the secondary physician's progress report (PR-2) on 1/27/15, the injured worker had complaints of nausea, constipation, and diarrhea. Abdomen was soft with normal bowel sounds. Diet recommendations were given. The requested treatments include Sentra AM, Sentra PM, and Probiotics.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**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 (ODG), Pain, Medical Food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain Chapter, Medical Foods.

**Decision rationale:** Based on the 01/2715 progress report provided by treating physician, the patient presents with nausea, constipation, and diarrhea. The request is for Sentra AM #60. Patient's diagnosis per Request for Authorization form dated 02/10/15 includes abdominal pain, acid reflux; constipation/diarrhea, rule out irritable bowel syndrome; hypertension; and sleep disorder, rule out obstructive sleep apnea. According to AME report dated 01/23/13, per 10/27/14 provider report, diagnosis included carpal tunnel syndrome, myofascial pain, and mild shoulder tendinosis. Treatment to date has included medication, diagnostics, orthopedic management, and psychiatric evaluation. Patient medications include Benazepril, Prilosec, Citrucel, Miralax, Probiotics, Sentra AM, and Sentra PM. Current work status not provided. The patient was deemed permanent and stationary from musculoskeletal stance, based on AME report dated 01/23/13, per 10/27/14 provider report. ODG, Pain Chapter under Medical Foods States: "Medical Food: intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must meet the following criteria: 1. The product must be a food for oral or tube feeding. 2. The product must be labeled for dietary management of a specific medical disorder. 3. The product must be used under medical supervision." Sentra AM was included in patient's medications, per provider report dated 02/10/15. Sentra AM is a medical food prescribed for sleep issues, fibromyalgia, and cognitive decline. In this case, the patient has a diagnosis of sleep disorder, but provided medical records do not indicate the patient has been diagnosed with a nutritional disorder, or that said supplement will be administered under medical supervision. Furthermore, there is no mention of choline deficiency secondary to liver deficiency in provided reports. Since use of Choline is not indicated for this patient, the request for Sentra AM cannot be recommended. Therefore, the request 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 (ODG), Pain, Medical Food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain Chapter, Medical Foods, Sentra PM.

**Decision rationale:** Based on the 01/2715 progress report provided by treating physician, the patient presents with nausea, constipation, and diarrhea. The request is for Sentra PM #60. Patient's diagnosis per Request for Authorization form dated 02/10/15 includes abdominal pain,

acid reflux; constipation/diarrhea, rule out irritable bowel syndrome; hypertension; and sleep disorder, rule out obstructive sleep apnea. According to AME report dated 01/23/13, per 10/27/14 provider report, diagnosis included carpal tunnel syndrome, myofascial pain, and mild shoulder tendinosis. Treatment to date has included medication, diagnostics, orthopedic management, and psychiatric evaluation. Patient medications include Benazepril, Prilosec, Citrucel, Miralax, Probiotics, Sentra AM, and Sentra PM. Current work status not provided. The patient was deemed permanent and stationary from musculoskeletal stance, based on AME report dated 01/23/13, per 10/27/14 provider report. ODG Guidelines, Pain Chapter under Medical Foods states: Medical food: Intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must meet the following criteria: (1) The product must be a food for oral or tube feeding, (2) The product must be labeled for dietary management of a specific medical disorder, (3) The product must be used under medical supervision not recommended for chronic pain. ODG Guidelines, Pain Chapter under Sentra PM States: Sentra PM is a medical food from [REDACTED], intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. ODG further states that for choline, there is no known medical need for choline supplementation. For glutamic acid, this supplement is used for treatment of hypochlorhydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer, and critical illnesses. It is generally used for digestive disorders and complementary medicine. For 5-hydroxytryptophan, the supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has been found to be effective for depression. Sentra PM was included in patient's medications, per provider report dated 02/10/15. In this case, the treating physician has prescribed Sentra PM which consists of choline bitartrate, glutamate, and 5-hydroxytryptophan. Both choline and glutamic acid are not supported by ODG Guidelines. Provider has not provided a medical rationale to prescribe a medical food that contains ingredients not supported by the ODG. Therefore, the request for the medical food Sentra PM is not medically necessary.

**Probiotics #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [cld.oxfordjournals.org/content/46/Supplement\\_2/S96.full.pdf](http://cld.oxfordjournals.org/content/46/Supplement_2/S96.full.pdf), Clinical Indications for Probiotics: An Overview.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain Chapter, Medical Foods, Journal of Therapeutic Advanced Gastroenterology 2010;3(5):307-319. Use of Probiotics in Gastrointestinal Disorders by Elizabeth C. Verna, MD, MSc, Susan Lucak.

**Decision rationale:** Based on the 01/27/15 progress report provided by treating physician, the patient presents with nausea, constipation, and diarrhea. The request is for Probiotics #60. Patient's diagnosis per Request for Authorization form dated 02/10/15 includes abdominal pain, acid reflux; constipation/diarrhea, rule out irritable bowel syndrome; hypertension; and sleep disorder, rule out obstructive sleep apnea. According to AME report dated 01/23/13, per

10/27/14 provider report, diagnosis included carpal tunnel syndrome, myofascial pain, and mild shoulder tendinosis. Treatment to date has included medication, diagnostics, orthopedic management, and psychiatric evaluation. Patient medications include Benazepril, Prilosec, Citrucel, Miralax, Probiotics, Sentra AM, and Sentra PM. Current work status not provided. The patient was deemed permanent and stationary from musculoskeletal stance, based on AME report dated 01/23/13, per 10/27/14 provider report. MTUS and ACOEM Guidelines do not address this request. ODG Guidelines, Pain Chapter under Medical Foods states: Medical food: Intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must meet the following criteria: (1) The product must be a food for oral or tube feeding, (2) The product must be labeled for dietary management of a specific medical disorder, (3) The product must be used under medical supervision not recommended for chronic pain. Journal of Therapeutic Advanced Gastroenterology 2010; 3(5):307-319. Use of Probiotics in Gastrointestinal Disorders by [REDACTED], [REDACTED] has the following: "The effect of probiotics on other GI disorders have also been studied, including lactose intolerance, Helicobacter pylori infection, microscopic colitis, prevention and treatment of diverticulitis, and even colon cancer prevention. The studies have been small and meta-analyses are too variable to draw firm conclusions of benefit...When added to standard therapy, probiotics do not provide additional benefit compared with standard therapy alone. Most probiotics tested to date are not more effective than placebo in inducing or maintaining IBD remission." Probiotics were included in patient's medications, per provider reports dated 01/27/15 and 02/10/15. Provider has not provided a reason for the request, other than subjective complaints of nausea and diagnosis of abdominal pain and acid reflux. Nonetheless, probiotics do not meet the criteria set by ODG for medical foods. Furthermore, there are no peer-reviewed studies available, which establish the efficacy of probiotic therapy as an effective treatment. Therefore, this request is not medically necessary.