

Case Number:	CM15-0131904		
Date Assigned:	07/20/2015	Date of Injury:	06/30/2001
Decision Date:	09/02/2015	UR Denial Date:	06/11/2015
Priority:	Standard	Application Received:	07/08/2015

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: New York
 Certification(s)/Specialty: Anesthesiology

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 63 year old female who sustained an industrial injury on 06-30-2001. Current diagnoses include constipation secondary to medications, hemorrhoids secondary to constipation, gastroesophageal reflux disease secondary to medications, gastritis secondary to medications, hypertension with left atrial enlargement triggered by the industrial injury, hyperlipidemia, diabetes mellitus triggered by the industrial injury, and sleep disorder secondary to pain and stress, rule out obstructive sleep apnea. Previous treatments included medications, psychiatric/psychological evaluation and treatment, surgical interventions, acupuncture, physical therapy, TENS unit. Report dated 05-12-2015 noted that the injured worker presented with complaints that included worsened gastroesophageal reflux symptoms, worsened gastritis, unchanged hypertension, diabetes mellitus, and unchanged sleep quality. Pain level was not included. Physical examination revealed blood pressure of 145 over 77 with medications, heart rate 101, blood glucose 181 (non-fasting), no significant findings on physical examination. Medication regimen included Nexium, Gaviscon, Citrucel, Victoza, probiotics, Preparation H cream, Metformin, Sentra AM, and Sentra PM. The treatment plan included re-request for re-evaluation for mouth guards, advised to continue a low-fat diet, low-acid, low-glycemic, low-cholesterol, low-sodium, and SIBO diet, follow up with primary care physician, and return in 3 months. Disputed treatments include probiotics, Sentra AM, and Sentra PM.

IMR ISSUES, DECISIONS AND RATIONALES

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

Probiotics #60 Refills: 2: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.ncbi.nlm.nih.gov/pubmed/22314561.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine (2014).

Decision rationale: Probiotics are microorganisms that are believed to provide health benefits when consumed. Commonly claimed benefits of probiotics include the decrease of potentially pathogenic gastrointestinal microorganisms, the reduction of gastrointestinal discomfort, the strengthening of the immune system, improvement of skin function, the improvement of bowel regularity, the strengthening of the resistance to cedar pollen allergens, the decrease of body pathogens, the reduction of flatulence and bloating, the protection of DNA, the protection of protein and lipids from oxidative damage, and the maintaining of individual intestinal microbiota in subjects receiving antibiotic treatment. In this case, there is no specific indication for probiotic therapy. Medical necessity for the requested item has not been established. The requested item is not medically necessary.

Sentra AM #60 3 bottles: 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 (Chronic), Medical food and Other Medical Treatment Guidelines Sentra Product Information.

Decision rationale: The California MTUS is silent regarding Sentra PM. The Official Disability Guidelines (ODG) does not recommend medical foods. "Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain." Sentra AM is a Medical Food that is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness and memory. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The request for Sentra AM is not medically necessary.

Sentra PM #60 3 bottles: 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 (Chronic), Sentra PM and Other Medical Treatment Guidelines Sentra Product Information.

Decision rationale: The California MTUS is silent regarding Sentra PM. The Official Disability Guidelines (ODG) does not recommend medical foods. "Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain." "Sentra PM is not recommended. It is a medical food intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. The medical records submitted do not indicate why this medical food is being recommended. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The request for Sentra PM is not medically necessary.