

Case Number:	CM14-0190596		
Date Assigned:	11/24/2014	Date of Injury:	01/17/2006
Decision Date:	01/09/2015	UR Denial Date:	10/20/2014
Priority:	Standard	Application Received:	11/14/2014

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 Emergency 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 patient is a 38-year-old male who was injured on January 17, 2006. The patient continued to experience pain in his back, abdominal bloating, and heartburn. Physical examination was notable for soft, non-tender, non-distended abdomen. Diagnoses included status post failed lumbar spine surgery, right-sided L5/S1 radiculopathy, and gastroesophageal reflux disease. Treatment included medications, epidural steroid injections, pool therapy, and surgery. Request for authorization for Sentra AM capsules was submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM CAP: 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 Chapter, Medical Foods

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Medical Food Other Medical Treatment Guideline or Medical Evidence: UpToDate: L-carnitine: Drug information

Decision rationale: Sentra AM is a medical food containing acetyl carnitine and choline. It 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. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally 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. Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. It is not recommended. Acetylcarnitine is a precursor for carnitine. Carnitine is a dietary supplement indicated for carnitine deficiency. There is no documentation of carnitine deficiency in this case. Carnitine is not recommended. Medical foods are not recommended for chronic pain. The request should not be authorized.