

Case Number:	CM15-0178813		
Date Assigned:	09/21/2015	Date of Injury:	10/28/2010
Decision Date:	10/28/2015	UR Denial Date:	08/24/2015
Priority:	Standard	Application Received:	09/11/2015

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 54 year old female, who sustained an industrial-work injury on 10-28-10. She reported initial complaints of poor sleep quality and occasional shortness of breath and palpitations. The injured worker was diagnosed as having hypertension, aggravated by industrial injury, sleep disorder, hyperlipidemia, ankle edema, and rule out arrhythmia. Treatment to date has included medication and diagnostics. Currently, the injured worker complains of sleep disturbance with sleep at 4 hours a night, occasional shortness of breath with activity, and palpitations. Medical history included hypertensive-arteriosclerotic retinopathy and hyperlipidemia, and history of CVA (cerebrovascular accident). Per the secondary treating physician's report on 7-7-15, exam notes alert and oriented, normal vital signs, clear lungs, normal bowel sounds with non-tender abdomen, and no clubbing, cyanosis, or edema to the extremities. Current plan of care includes lab testing, medication, and pending MRI (magnetic resonance imaging). There was recommendation or weight loss and a low cholesterol no sodium, no caffeine diet. The Request for Authorization requested service to include Sentra AM #60 3 bottles. The Utilization Review on 8-24-15 denied the request due to lack of support for use of this oral supplement, per non-MTUS: www.fda.gov.

IMR ISSUES, DECISIONS AND RATIONALES

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

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 www.fda.gov.

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, under Medical Food.

Decision rationale: The current request is for Sentra AM #60 3 bottles. The RFA is dated 07/07/15. Treatment history includes medications. The patient's work status is not addressed. The MTUS and ACOEM Guidelines do not address this request. Official Disability Guidelines, Pain chapter, under Medical Food has the following: Not recommended for chronic pain. 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 eternally 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: 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. Per report 07/07/15, the patient continues to have sleep disturbance with only 4 hours of sleep per night. She also complains of occasional shortness of breath with activity, and palpitations. Treatment plan was for lab testing, and medications including Sentra AM, #30 3 bottles. Nutritional supplements such as Sentra AM are sometimes prescribed for cognitive disorders secondary to Choline deficiency. While the provider discusses sleep disturbances, there are no diagnoses addressing Choline nutritional deficiency, liver disease, or examination findings which support such a conclusion. Since the use of Choline is not indicated for this patient, the request for Sentra AM cannot be recommended. Therefore, the request is not medically necessary.