

Case Number:	CM14-0187836		
Date Assigned:	11/18/2014	Date of Injury:	06/29/2006
Decision Date:	01/06/2015	UR Denial Date:	11/05/2014
Priority:	Standard	Application Received:	11/11/2014

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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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:

This patient is a 48 year old employee with date of injury 6/29/06. Medical records indicate the patient is undergoing treatment for cervical spine herniated nucleus pulposus, thoracic spine herniated nucleus pulposus and lumbar spine herniated nucleus pulposus. Subjective complaints include neck and med back pain with burning sensation and sensitivity to touch in upper extremities. Low back pain with stiffness, burning sensation and sensitivity to touch in the lower extremities. She has cervical spine pain radiating to both shoulders to wrists. She has thoracic non-radiating pain and lumbar pain that radiates to right thigh. Pain level 8/10 without medications and 5/10 with medications. Complains of difficulty sleeping, stress, heartburn and headaches. Objective complaints include stiffness over cervical spine with limited ROM and weakness lower extremities. Muscle guarding over thoracic spine paraspinal muscles. The physician noted decreased sensation at C5 and C6 dermatomes on the right and C5-C7 dermatomes on the left. Noted decreased motion and spasm at the cervical, thoracic and lumbar spine. Straight leg raise negative. Spurling's sign and axial head compression test were positive bilaterally; weakness in lower extremities; gait is wide based; EMG/NCV was normal. Treatment has consisted of acupuncture which afforded significant pain relief lasting 2 months. PT, Chiropractic and home exercise program. Epidural steroid injections L3-4 and L4-5. Medications are Tramadol, Diclofenac, Omeprazole, Cyclobenzaprine, Mirtazapine, Methoderm, Percura, Compounded (unclassified) prescription and Sentra PM. The utilization review determination was rendered on 11/5/14 recommending non-certification of Sentra AM #60.

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), 19th Annual Edition, and 12th Annual Edition, 2014, Pain Chapter, 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, Medical Food

Decision rationale: Sentra AM is a medical food that contains choline and acetylcarnitine as in intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. In addition ODG states that a medical food is "Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) 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. To be considered the product must, at a minimum, 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, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision." ODG specifically states "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." Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra AM #60 is not medically necessary.