

Case Number:	CM15-0016131		
Date Assigned:	04/07/2015	Date of Injury:	04/20/2008
Decision Date:	05/07/2015	UR Denial Date:	12/30/2014
Priority:	Standard	Application Received:	01/28/2015

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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 (IW) is a 62-year-old female who sustained an industrial injury on 04/20/2008. She reported back pain. The injured worker was diagnosed as having a lumbosacral injury for which she underwent an anterior fusion. According to the agreed on medical examination of 11/26/2014, treatment to date has included an anterior fusion and a posterior fusion, a hardware replacement, and an additional disc surgery. Her industrial related diagnoses listed in the provider visit of 11/19/2014 are sleep disorder; history of hypertension (controlled); abdominal pain; constipation; blurred vision, bilateral (more frequent in left eye); glucose intolerance; hypertriglyceridemia. Currently, the injured worker complains of gastric complaints and fatigue. A request for authorization was submitted for 30 Crestor, a prescription Sentra AM #60 (3 bottles), a prescription Sentra PM #60 (3 bottles), an abdominal ultrasound, cardio-respiratory testing and Sudo-scan, and a follow up in 3 months.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prescription 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.

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 Prescription Sentra AM #60 (3 bottles) is not medically necessary.

Prescription 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.

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: MTUS is silent regarding Sentra PM. ODG states that 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. 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 Prescription Sentra PM #60, (3 bottles) is not medically necessary.