

Case Number:	CM15-0002443		
Date Assigned:	01/13/2015	Date of Injury:	01/30/2011
Decision Date:	03/10/2015	UR Denial Date:	12/19/2014
Priority:	Standard	Application Received:	01/06/2015

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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & Gen Prev Med

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 59 year old female, who sustained an industrial injury on 01/30/2011. She has reported right shoulder pain and low back pain. The diagnoses have included displacement of cervical intervertebral disc without myelopathy, displacement of lumbar intervertebral disc without myelopathy, bilateral upper extremity radiculopathy and bilateral lower extremity radiculopathy (per the eval dated 11/10/2014), and acid reflux secondary to stress and sleep disorder, rule out obstructive sleep apnea. Treatment to date has included epidural steroid injections, medications, conservative treatments, diet changes, and psychiatric therapy. Currently, the injured worker complained of cervical spine pain (4/10), lumbar spine pain (8/10), right shoulder pain (6/10). She also reported (exam dated 10/30/2014) improving acid reflux symptoms although they were still present, especially without medications or changes in diet. The injured worker also noted improvement in sleep pattern with 5-6 hours of sleep and waking up about 4 times each night due to pain. The injured worker has recently been treated with Gaviskon, Nexium, simethicone and probiotics. There was no recent gastric testing noted. On 12/18/2014, Utilization Review non-certified a prescription for Sentra PM #60, 3 bottles between 10/30/2014 and 02/09/2015, noting the lack of guideline support for medical food (such as Sentra PM) in the treatment for chronic pain. Non- MTUS, ACOEM Guidelines, was cited. On 01/06/2015, the injured worker submitted an application for IMR for review of Sentra PM #60, 3 bottles.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra PM quantity 60 quantity 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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation 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 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. As such, the request for Sentra PM, 60 quantity, 3 bottles is not medically necessary.