

Case Number:	CM15-0180671		
Date Assigned:	09/23/2015	Date of Injury:	01/25/1995
Decision Date:	10/27/2015	UR Denial Date:	08/24/2015
Priority:	Standard	Application Received:	09/14/2015

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: New Jersey, New York
 Certification(s)/Specialty: Family Practice

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 60 year old male sustained an industrial injury on 1-25-95. Documentation indicated that the injured worker was receiving treatment for chronic lumbar, cervical and right shoulder pain. Past medical history was significant for hypertension and diabetes mellitus. Recent treatment consisted of medication management and home exercise. In a PR-2 dated 6-16-15, the injured worker complained of continuing neck, back and right shoulder pain, rated 6 out of 10 of 10 on the visual analog scale. The injured worker stated that medications allowed him to continue to perform activities of daily living. The physician stated that Sentra AM was prescribed to manage fatigue and cognitive dysfunction related to a shift in metabolic processes that occurred due to the injury with subsequent dietary deficiencies. In a PR-2 dated 8-11-15, the injured worker complained of ongoing right shoulder, neck and back pain, rated 6 out of 10 of 10 on the visual analog scale. Physical exam was remarkable for bilateral tenderness to palpation, trigger points and spasms to the cervical spine and lumbar spine paraspinal musculature and trapezius muscle with decreased range of motion, 5 out of 5 strength to bilateral upper and lower extremities, "decreased" sensation to bilateral legs and "decreased" bilateral deep tendon ankle reflexes. The treatment plan included continuing home exercise and continuing medications (Naproxen Sodium, Norco, Fenniprofen, Theramine, Sentra AM and Sentra pm. On 8-24-15, Utilization Review noncertified a request for Sentra AM twice a day #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM twice a day #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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 and Other Medical Treatment Guidelines FDA section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

Decision rationale: Sentra PM is a medical food that is used for sleep disorders associated with depression. The ingredients include neurotransmitter precursors (choline bitartrate, glutamate, and 5-hydroxytryptophan); polyphenolic antioxidants (hawthorn berry, cocoa); an amino acid uptake stimulator (gingko biloba); activators of amino acid utilization (acetyl-L-carnitine, glutamate, cocoa powder); and an adenosine antagonist (cocoa powder). The FDA defines medical food in section 5(b) of the Orphan Drug Act (21 U.s.c. 360 ee (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. Sentra PM does not meet the requirement for medical food as stated by the FDA. There is no documented nutritional deficiency for which a medical food is required. For the patient, there is no documentation of sleep disorders or depression, as well as a documented discussion of proper sleep hygiene. Therefore, Sentra PM is not considered medically necessary.