

<b>Case Number:</b>	CM15-0169158		
<b>Date Assigned:</b>	09/09/2015	<b>Date of Injury:</b>	11/03/2014
<b>Decision Date:</b>	10/14/2015	<b>UR Denial Date:</b>	07/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/27/2015

### 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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 40-year-old male, who sustained an industrial injury on November 4, 2014. He reported headaches, neck pain, bilateral upper extremity pain, numbness and tingling, mid back pain, low back pain and bilateral shoulder pain. The injured worker was diagnosed as having headaches, bilateral shoulder sprain and strain and cervical, thoracic and lumbar spine sprain and strain. Treatment to date has included diagnostic studies, radiographic imaging, Sudomotor scan, and physical therapy x6 sessions, conservative care, medications and work restrictions. Currently, the injured worker continues to report headaches, neck pain, bilateral upper extremity pain, numbness and tingling, mid back pain, low back pain and bilateral shoulder pain. The injured worker reported an industrial injury in 2014, resulting in the above noted pain. He was treated conservatively without complete resolution of the pain. The PR-2 on February 4, 2015, revealed continued pain as noted. He rated his pain using a visual analog scale (VAS) from 1-10 with 10 being the worst. He rated his pain at 6-8 on the VAS. Suprspinatus test was positive on the right and there was noted tenderness and muscle spasm along the trapezius. The lumbar spine was tender to palpation and the straight leg test was positive bilaterally. The home exercise plan and medications including Somnicin were continued. Urinary drug screen on March 4, 2015, revealed findings consistent with expectations. Sudomotor function assessment diagnostic report on March 4, 2015, revealed abnormal hand symmetry, but normal conductance levels. The PR-2 on March 4, 2015, revealed continued pain as noted. He rated his pain at 5-9 on the VAS. It was noted medications helped the injured worker walk, sit and sleep longer. There was no other indication of a sleep assessment on this report. Evaluation on June 8, 2015,

revealed continued pain as noted. He continued to rate his pain at 6 on the VAS and noted the headaches were constant. There was no indication of sleep disruption. Evaluation on July 14, 2015, revealed continued pain rated at 6 on the VAS. He continued to be temporarily totally disabled and was not working. There was no diagnosis of insomnia and no sleep assessment of sleep hygiene. The RFA included a request for Sentra PM cap #60 and was non-certified on the utilization review (UR) on July 29, 2015.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Sentra PM cap #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM Guidelines 2007 revision low back chapter, page 125, 7; Official Disability Guidelines (ODG) Pain Chapter, updated 02/23/15.

**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 is not medically necessary.