

<b>Case Number:</b>	CM15-0163888		
<b>Date Assigned:</b>	09/01/2015	<b>Date of Injury:</b>	11/18/2013
<b>Decision Date:</b>	09/30/2015	<b>UR Denial Date:</b>	07/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/20/2015

### 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 & General Preventive 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 44 year old male who sustained an industrial injury on 11-18-2013. He was lifting a heavy object when he felt a painful poop in the low back. He has reported low back pain and right lower extremity pain associated with numbness and tingling and has been diagnosed with sprain strain lumbar spine with right lower extremity radiculopathy, and erectile dysfunction with underlying herniated disc at L4-L5 per MRI, sprain strain, right knee, and sleep disturbance. Treatment has included acupuncture, TENS, medical imaging, medications, physical therapy, aqua therapy, and chiropractic care. There was tenderness to palpation over the right paralumbar muscles. Palpation of the right sciatic notch produced pain radiating to the right leg. There was mild atrophy noted on the right leg. There was tenderness to palpation over the medial joint line. McMurray's test was positive for medical meniscus abnormality. The treatment plan included physical therapy, chiropractic treatment, and home treatment. The treatment request included Sentra AM cap # 60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra AM CAP #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACEOM Guidelines 2007 Low Back Chapter page 125; Official Disability Guidelines (ODG) Pain Chapter updated 06/15/2015; OMFS page 7.

**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 CAP #60 is not medically necessary.