

<b>Case Number:</b>	CM15-0137198		
<b>Date Assigned:</b>	07/27/2015	<b>Date of Injury:</b>	07/21/2000
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	07/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/15/2015

### 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: California

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 69 year old male, who sustained an industrial injury on 7/21/2000. The mechanism of injury is unclear. The injured worker was diagnosed as having flare-up of lumbar radiculitis, failed back syndrome, lumbosacral intervertebral disc degeneration. Treatment to date has included medications. He is retired. The request is for Sentra PM, and Sentra AM. On 12/1/2014, he complained of persistent low back pain. He rated his pain 5/10 with medications and 9-10/10 without medications. Physical findings revealed tenderness in the low back. The treatment plan included: refills for Prilosec, Docuprene, Neurontin, and morphine sulfate. On 7/6/2015, he complained of bilateral feet tingling. He reported stopping Gabapentin as the burning sensation in his feet is improved. He rated his low back pain as 5/10. No aberrant behaviors are noted and no adverse effects were noted. The treatment plan included: Sentra AM and Sentra PM. Sentra AM is noted to help with alertness and energy; and Sentra Pm is noted to help with sleep. His other medications are: Morphine sulfate, Docusate, Prilosec, Lidocaine patch, Cymbalta for sleep and depression, and Theramine.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra PM (Rx 07/06/15): 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 Chapter/Sentra PM Section.

**Decision rationale:** MTUS guidelines do not address the use of Sentra PM. Per the ODG, Sentra PM is not recommended. Sentra PM is a medical food from [REDACTED] intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. See Medical food, Choline, Glutamic Acid, & 5-hydroxytryptophan. As Sentra PM is not supported by the established guidelines, the request for Sentra PM (Rx 07/06/15) is determined to not be medically necessary.

**Sentra AM (Rx 07/06/15): 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 Chapter/Medical Food Section, Choline Section and Other Medical Treatment Guidelines [http://nutrientpharmacology.com/sentra\\_AM.html](http://nutrientpharmacology.com/sentra_AM.html).

**Decision rationale:** The MTUS guidelines and ODG so not address the use of Sentra AM specifically but the ODG does address the use of the medical food, Choline which is a key ingredient in Sentra AM. Per manufacturer's information, Sentra AM is a Medical Food used to manage fatigue and deficiencies associated with memory and concentration. Sentra AM provides the nutrients required by the brain to reduce fatigue. Sentra AM is used as part of a program to manage acute and chronic fatigue and is designed to improve mental awareness. Sentra AM is used as part of a program to manage fibromyalgia. A key ingredient in this product is Choline. Per the ODG, 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. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. In this case, there is no evidence of chronic fatigue or fibromyalgia in the injured worker. Additionally, Choline is not recommended by the established guidelines, therefore, the request for Sentra AM (Rx 07/06/15) is determined to not be medically necessary.