

<b>Case Number:</b>	CM14-0215489		
<b>Date Assigned:</b>	01/05/2015	<b>Date of Injury:</b>	08/08/2003
<b>Decision Date:</b>	02/25/2015	<b>UR Denial Date:</b>	11/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/23/2014

### 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 York, Pennsylvania, Washington  
 Certification(s)/Specialty: Internal Medicine, Geriatric 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 72 year old woman with a date of injury of 8/8/03. A sleep study from 2008 showed mild apnea/hypopnea. Her diagnoses included major depressive disorder, diabetes, osteoarthritis, chronic pain. There are no other records that document sleep related diagnoses. At issue in this review are the medications: sentra pm and theramine with dates of service from February and March of 2009.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective (DOS 3/17/09) Sentra PM Cap290/40mg #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG 2014 Medical food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Uptodate: treatment of insomnia [http://nutrientpharmacology.com/sentra\\_AM.html](http://nutrientpharmacology.com/sentra_AM.html) and

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods>

**Decision rationale:** Sentra PM is a medication food. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally 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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. Additionally, patients with insomnia should receive therapy for any medical condition, psychiatric illness, substance abuse, or sleep disorder that may cause the problem and be counseled regarding sleep hygiene. After this, cognitive behavioral therapy would be used prior to medications. In this injured worker, the sleep pattern, hygiene or level of insomnia is not addressed. There is a sleep study showing mild apnea but no documentation of whether this was treated. The documentation does not support the medical necessity for Sentra PM.

**Retrospective (DOS 2/10/09) Theramine caps 101.5mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG 2014 Medical food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA website:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

**Decision rationale:** Theramine is a medical food used to treat chronic pain syndromes and low back pain. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally 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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. The request for Theramine is not medically necessary.

**Retrospective (DOS 2/10/09) Sentra PM cap 290/40mg #60 x2: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG 2014 Medical food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical

Evidence: Uptodate: treatment of insomnia [http://nutrientpharmacology.com/sentra\\_AM.html](http://nutrientpharmacology.com/sentra_AM.html) and

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

**Decision rationale:** Sentra PM is a medication food. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally 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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. Additionally, patients with insomnia should receive therapy for any medical condition, psychiatric illness, substance abuse, or sleep disorder that may cause the problem and be counseled regarding sleep hygiene. After this, cognitive behavioral therapy would be used prior to medications. In this injured worker, the sleep pattern, hygiene or level of insomnia is not addressed. There is a sleep study showing mild apnea but no documentation of whether this was treated. The documentation does not support the medical necessity for requested Sentra PM.