

<b>Case Number:</b>	CM14-0109361		
<b>Date Assigned:</b>	08/01/2014	<b>Date of Injury:</b>	09/26/2011
<b>Decision Date:</b>	10/16/2014	<b>UR Denial Date:</b>	06/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/14/2014

### 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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in New Jersey. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 worker is a 49 year old male who was injured on 9/26/2011. He was diagnosed with cervical radiculopathy, lumbar radiculopathy, and muscle spasm. He was treated with opioids, sedative hypnotics for sleep, antidepressants, muscle relaxants, NSAIDs, and medical food supplements including Theramine, Sentra AM, and Sentra PM. The worker was seen by his primary treating physician on 6/2/14 complaining of his chronic but worsening neck and lumbar pain. He reported having recently started taking Theramine, Sentra AM, and Sentra PM which had been helpful "with allowing his Lunesta work better at night and sleep better." He was then recommended to continue his medications and medical food supplements. The Theramine was indicated to help "absorption of NSAID and meds", the Sentra PM for his "sleep and energy", and the Sentra AM to "help with alertness and energy."

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra PM twice a day, quantity 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, (updated 06/10/14), Medical food, Sentra PM

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Sentra PM, Medical food

**Decision rationale:** The MTUS Guidelines are silent in regards to the medical food supplement, Sentra PM, which is made by Targeted Medical Pharma, Inc. The Official Disability Guidelines, however, states that Sentra PM contains a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, and is intended for the use in management of sleep disorders associated with depression, but is not generally recommended for chronic pain as it has not been shown to produce a meaningful benefit. Due to this product not being recommended by the Official Disability Guidelines, in the case of this worker, it is not medically necessary.

**Sentra AM twice a day quantity 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (updated 06/10/14), Medical food

**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 on Physician Therapeutics, Sentra AM (<http://www.ptlcentral.com/medical-foods-products.php>)

**Decision rationale:** Sentra AM is a medical food product which contains various ingredients including choline, arginine, GABA, histidine, tryptophan, and serine, and is marketed for the treatment of fatigue and cognitive disorders. The MTUS is silent regarding Sentra AM or its ingredients individually. The Official Disability Guidelines, however, states that medical food may be recommended in certain situations where there is a distinctive nutritional requirement. Choline, the primary ingredient in Sentra AM is only recommended for long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency, and is not generally recommended yet for other indications. Choline and these other amino acids are found in foods, which can be prescribed to patients as well, so there is no need for a specific product for most patients. In the case of this worker, he had been prescribed Sentra AM for his alertness, but due to Official Disability Guidelines not recommending this product in general, it is not medically necessary.

**Theramine three times a day quantity 90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (updated 06/10/14), Theramine, Medical food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Theramine

**Decision rationale:** The MTUS Guidelines are silent when it comes to use of Theramine. Theramine is a medical food product that includes a variety of amino acids, GABA, 5-HTP, and other ingredients, and is used in the management of pain syndromes. The Official Disability Guidelines states that Theramine is not recommended as there is no high quality peer-reviewed literature that shows that these ingredients are effective. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended, according to the Official Disability Guidelines. In the case of this worker, Theramine was prescribed for better absorption of his medications, which is not understood by the reviewer. Regardless, due to Theramine not being generally recommended by the Official Disability Guidelines, it is not medically necessary.