

<b>Case Number:</b>	CM14-0074205		
<b>Date Assigned:</b>	09/18/2014	<b>Date of Injury:</b>	01/21/1997
<b>Decision Date:</b>	10/16/2014	<b>UR Denial Date:</b>	05/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/21/2014

### 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 52 year old male who was injured on 1/21/1997. He was diagnosed with lumbar radiculopathy and muscle spasm. He was treated with H-wave, opioids, TENS unit, physical therapy, muscle relaxants, antidepressants, acupuncture, and topical analgesics. On 3/4/14, the worker was seen by his treating physician complaining of increased pain and a reported consuming more medications as a result. On physical examination, there was decreased sensory left lateral leg and right posterior leg unable to balance on the left leg. He was then recommended to continue Soma, Lortab, home exercise, Ketoprofen cream, and start the medical foods Theramine, Sentra PM, and Sentra AM. He was also advised to stop using Tylenol. Later, on 4/29/14, the worker returned to his treating physician reporting continual back spasms. The medical foods prescribed to him reportedly help the worker to taper off of Tylenol PM. Physical examination revealed lumbar muscle spasm and tenderness with decreased range of motion as well as decreased sensation of the left lateral leg and right posterior leg with inability to balance on the left leg. He was then recommended to continue his use of his medications, home exercises, and continue his Theramine, Sentra PM, and Sentra AM.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine #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 Pain Chapter Theramine

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain section, 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 ODG 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 ODG. In the case of this worker, he had used Theramine for many weeks with some reported ability to reduce use of Tylenol PM, but it is unclear as to which medical food prescribed contributed the most to this benefit. Regardless, Theramine is generally not recommended by the MTUS and is not medically necessary.

**Sentra AM #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 Pain Chapter: Medical Foods

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Section, Medical food Other Medical Treatment Guideline or Medical Evidence: 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 ODG, 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, Sentra AM was used for many weeks leading up to this request, but no report was made on its benefit besides possibly contributing to the worker's decrease in Tylenol PM use, but it is unclear as to which medical food prescribed contributed the most to this benefit. Either way, the use of Sentra AM and its ingredients is not generally recommended by the MTUS and is not medically necessary.

**Sentra PM #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 Pain Chapter: Medical Foods

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

**Decision rationale:** The MTUS Guidelines are silent in regards to the medical food supplement, Sentra PM, which is made by [REDACTED]. The ODG, 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. In the case of this worker, he was using this medical food for weeks leading up to this request. His use of Sentra PM and other medical foods were reported to help him reduce his Tylenol PM use, but it is unclear as to which medical food contributed to this benefit. However, as this medical food is generally not recommended by the MTUS, it is not medically necessary.