

<b>Case Number:</b>	CM13-0036392		
<b>Date Assigned:</b>	12/27/2013	<b>Date of Injury:</b>	10/13/2000
<b>Decision Date:</b>	03/06/2014	<b>UR Denial Date:</b>	09/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/21/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine and is licensed to practice in New York. 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 physician 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 claimant is a 53 year old female who sustained an injury on October 13, 2000. Her diagnoses include cervical and lumbar disopathy, status post (s/p) L5-S1 fusion, cervical strain/sprain, obesity, hypertension, and depression. On exam she has complaints of neck and bilateral upper extremity pain, and ongoing low back pain. Physical exam demonstrates spasm and tenderness over the neck and lumbar spine with reduced range of motion. The treating provider has requested Theramine, #90; App-Trim-D, #120; and Sentra PM, #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**The request for Theramine, #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Theramine is a compound medical food and is a formulation, which includes neurotransmitter precursors, neurotransmitters, and anti-inflammatory and immunomodulatory peptides. Theramine is intended for use in the management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. According to the

California MTUS guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended as a whole. Theramine contains GABA, Choline, and L-Arginine, which are not recommended by the California MTUS guidelines. The medical necessity for the requested treatment has not been established. Therefore the requested treatment is not medically necessary.

**The request for AppTrim-D, #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines - Treatment for Workers' Compensation, Online Edition, Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine 2012- Pharmacotherapy for Diet.

**Decision rationale:** AppTrim-D provides amino acids that are known to suppress Neuropeptide Y, the hormone that controls hunger. The patient is not enrolled in a medically supervised weight loss program. There is no documentation indicating that App-Trim is medically proven to result in significant and sustained weight loss. According to the FDA, medical foods such as App-Trim may only be used when a patient is under the ongoing care of a physician or other healthcare provider. The medical necessity for the requested treatment has not been established. Therefore the requested treatment is not medically necessary.

**The request for Sentra PM, #60:** 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 Sentra AM product Information.

**Decision rationale:** Sentra PM is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, neurotoxicity-induced fatigue syndrome and cognitive impairment involving arousal, alertness, and memory. It is a medical food that must be used under the supervision of a physician. There is no documentation provided indicating the patient has any of the above conditions and that any food supplement is required to provide a balance of this product's specific components to meet any increased requirements of muscle dysfunction, sleep disturbances, cognitive impairment, and chronic stress. The medical necessity for the requested treatment has not been established. Therefore the requested treatment is not medically necessary.