

<b>Case Number:</b>	CM14-0077012		
<b>Date Assigned:</b>	07/18/2014	<b>Date of Injury:</b>	06/17/2012
<b>Decision Date:</b>	09/17/2014	<b>UR Denial Date:</b>	04/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/27/2014

### 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 Emergency 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 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 patient is a 40-year-old male who was injured on June 17, 2012. The patient continues to experience pain in his back and right shoulder. Physical examination was notable for bilateral tenderness and spasm of the supraspinatus muscles, decreased range of motion of the lumbar spine, normal motor function, and decreased sensation to pinprick along the right lateral leg. Diagnoses included right shoulder supraspinatus tear, lumbar disc disease, and muscle spasm. Treatment includes medications. Requests for authorization for Theramine # 90, Sentra AM #60 and Sentra PM # 60 were submitted for consideration.

### 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 (ODG) Official Disability Guidelines Treatment for Worker's Compensation, Online Edition Pain (Chronic).

**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, Medical Food.

**Decision rationale:** Theramine is a medical food that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Medical Food 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 are established by medical evaluation. GABA is indicated for epilepsy, spasticity and tardive dyskinesia. There is no documentation that any of these conditions are present in the patient. 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. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects such as sweating and diarrhea. There is no indication for the use of serine. Arginine is not indicated in current references for pain or inflammation. Theramine is not recommended under ODG. The request 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 (ODG) Official Disability Guidelines Treatment for Worker's Compensation, Online Edition Pain (Chronic).

**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 Other Medical Treatment Guideline or Medical Evidence: UpToDate: Carnitine metabolism in renal disease and dialysis.

**Decision rationale:** Sentra AM is used to manage fatigue and deficiencies associated with memory and concentration. Medical Food 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. 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. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects such as sweating and diarrhea. Glutamic acid (glutamate) is a supplement used for treatment of hypochlorhydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. The patient is not suffering from these conditions. Acetylcarnitine is a precursor to L-carnitine. The patient is not suffering from these conditions. Acetylcarnitine is not recommended. This medical food contains ingredients that are not recommended. The request 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 (ODG) Official Disability Guidelines Treatment for Worker's Compensation, Online Edition Pain (Chronic).

**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, Sentra PM.

**Decision rationale:** Sentra PM is a medical food intended for use in management of sleep disorders associated with depression. Medical Food 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 established by medical evaluation. 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. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects such as sweating and diarrhea. Glutamic acid glutamate is a supplement used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. The patient is not suffering from these conditions. Glutamate is not recommended. 5-hydroxytryptophan is a supplement that has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. There is no documentation that the patient is suffering from any of these conditions. 5-hydroxytryptophan is not recommended. This medical food contains ingredients that are not recommended. The request is not medically necessary.