

<b>Case Number:</b>	CM15-0131950		
<b>Date Assigned:</b>	07/20/2015	<b>Date of Injury:</b>	08/08/2012
<b>Decision Date:</b>	08/31/2015	<b>UR Denial Date:</b>	06/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/08/2015

### 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, Tennessee  
 Certification(s)/Specialty: Emergency 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 61 year old male, who sustained an industrial injury on 8-8-12. He has reported initial complaints of a left knee injury and syncopal episode after stepping into a pothole. The diagnoses have included hypertension. Treatment to date has included medications activity modifications, acupuncture, blood pressure monitoring, labs, diagnostics and off of work. Currently, as per the physician progress note dated 5-14-15, the injured worker complains of blood pressure that has remained unchanged. The physical exam reveals blood pressure is 188 over 83 with medication and second blood pressure is 160 over 83. The height is 5 feet 3 inches and weight is 206 pounds. The remainder of the physical exam is unremarkable. The diagnostic testing that was performed included 2D echocardiogram. The current medications included hydrochlorothiazide, Lisinopril, Aspirin and Crestor. The physician requested treatments included Sentra PM, Sentra AM and Crestor 10mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra PM Qty: 60 x 3 bottles: 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 04/30/2015).

**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 Other Medical Treatment Guidelines Up-to-date: L-carnitine: Drug information Up-to-date: Clinical use of ginkgo biloba.

**Decision rationale:** Sentra PM is a medical food containing acetyl carnitine, glutamate, ginkgo biloba, 5-hydroxytryptophan and choline. It is intended for use in management of sleep disorders associated with depression. FDA defines a medical food as a food which is formulated to be consumed or administered internally 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. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Acetylcarnitine is a precursor for carnitine. Carnitine is a dietary supplement indicated for carnitine deficiency. There is no documentation of carnitine deficiency in this case. Carnitine is not recommended. 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. It is generally used for digestive disorders in complementary medicine. It is not recommended. 5-hydroxytryptophan is a supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, and obesity and sleep disorders. It has been found to be effective for depression. In alternative medicine, it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. It is not recommended. Ginkgo biloba, more commonly known as ginkgo, has been used medicinally for over 1000 years. It has been used for the treatment of dementia, age-related memory impairment, and depression. Studies have not found it effective in dementia. There is preliminary evidence that it useful in depression and anxiety. It is not recommended. 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. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. It is not recommended. This medical foods are contains ingredients that are not recommended. It is therefore not recommended. In this case the patient suffered heat stroke resulting in a fall with injury to neck, right shoulder, and left knee. The request is not medically necessary.

**Sentra AM Qty: 60 x 3 bottles:** 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 04/30/2015) Online Version.

**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 Other Medical Treatment Guidelines Up-to-date: L-carnitine: Drug information.

**Decision rationale:** Sentra AM is a medical food containing acetyl carnitine and choline. It is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory. FDA defines a medical food as a food which is formulated to be consumed or administered internally 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. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. 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. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. It is not recommended. Acetylcarnitine is a precursor for carnitine. Carnitine is a dietary supplement indicated for carnitine deficiency. There is no documentation of carnitine deficiency in this case. Carnitine is not recommended. Medical foods are not recommended for chronic pain. In this case the patient suffered heat stroke resulting in a fall with injury to neck, right shoulder, and left knee. The request is not medically necessary.

**Crestor 10mg Qty:30 with 2 refills:** 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) Diabetes (updated 05/16/2015) Online Version.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation, The Medical Letter: Treatment Guidelines from the Medical Letter, Issues 137, January 1, 2014.

**Decision rationale:** Crestor is Rosuvastatin, a medication used as an adjunct to diet and exercise to control hyperlipidemia. Statins can reduce the risk of a cardiovascular event and are generally well tolerated. Medications are used as an adjunct if diet and exercise adjustments are not successful. In this case there is no documentation that the patient is using dietary measures to control his hyperlipidemia. The request is not medically necessary.