

<b>Case Number:</b>	CM14-0152481		
<b>Date Assigned:</b>	09/22/2014	<b>Date of Injury:</b>	02/17/2010
<b>Decision Date:</b>	10/21/2014	<b>UR Denial Date:</b>	08/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/18/2014

### 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 Occupational Medicine and is licensed to practice in California. 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:

This is a 42-year-old male with a 2/17/10 date of injury. The mechanism of injury occurred when his glove got caught in a drill bit and his hand and arm were twisted. According to a progress report dated 8/19/14, the patient described left shoulder pain that was constantly moderate to severe and aggravated with movements, rated as a 9/10. He also complained of neck pain, rated 9/10 and lumbar spine pain, rated 7-8/10. Objective findings: limited range of motion of cervical spine with paraspinal muscle tenderness and spasms. Diagnostic impression: cervical disc protrusion, left shoulder impingement, and status post left shoulder surgery. Treatment to date: medication management, activity modification, physical therapy, surgery. A UR decision dated 8/27/14 denied the requests for Theramine and Sentra. Medical necessity is not established. FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. In addition, there is no rationale or indication provided for the treatment with the requested medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Medical Foods: 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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Other Medical Treatment Guideline or Medical Evidence: FDA (Theramine)

**Decision rationale:** CA MTUS does not address this issue. However, the FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. According to the FDA, Theramine is a specialized formula that consists of: Choline Bitartrate, L-arginine, L-histidine HCL, L-glutamine, L-serine, GABA, Griffonia Seed (95% 5HTP), Whey Protein Hydrolysate, Grape Seed Extract (85% Polyphenols), Cinnamon, and Cocoa Extract (6% Theobromine). There is no documentation in the reports reviewed addressing why Theramine has been prescribed. A specific rationale identifying why Theramine would be required in this patient despite lack of guideline support was not provided. Therefore, the request for Medical foods: Theramine #90 was not medically necessary.

**Medical Foods:. Sentra #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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Other Medical Treatment Guideline or Medical Evidence: <http://www.ptlcentral.com/medical-foods-products.php>

**Decision rationale:** CA MTUS does not address this issue. However, the FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. In addition, there is no rationale or indication provided for the treatment with the requested medications. According to an online search, Sentra is a specially formulated prescription only Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the dietary management of the altered metabolic processes of sleep disorders associated with depression. There is no documentation in the reports reviewed addressing why Sentra has been prescribed. A specific rationale identifying why Sentra would be required in this patient despite lack of guideline support was not provided. Therefore, the request for Medical Foods: Sentra #60 was not medically necessary.