

<b>Case Number:</b>	CM15-0061690		
<b>Date Assigned:</b>	04/07/2015	<b>Date of Injury:</b>	08/13/2008
<b>Decision Date:</b>	05/06/2015	<b>UR Denial Date:</b>	03/04/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/01/2015

### 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: Massachusetts

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

### 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 32 year old male sustained an industrial injury on 8/13/08. He subsequently reported shoulder pain. Diagnoses include pain in joint, shoulder region, unspecified and joint derangement, shoulder region. Diagnostic testing has included nerve conduction study. Treatments to date have included prescription pain medications. The injured worker continues to experience left shoulder pain. A request for Theramine, Sentra and Gabadone medications made by the treating physician.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine #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 (Chronic), Theramine.

**Decision rationale:** The claimant sustained a work-related injury in August 2008 and continues to be treated for chronic left shoulder pain. Theramine is a medical food from that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Guidelines recommend against its use. Therefore, the requested treatment 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

<http://www.marvistahealthcenter.com/medicalfoods/SentraAMProductMonograph.pdf>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Medical Food.

**Decision rationale:** The claimant sustained a work-related injury in August 2008 and continues to be treated for chronic left shoulder pain. Sentra AM is a medical food intended for use in the management of fatigue, memory disorders and vascular dementia. It is a proprietary blend of choline bitartrate, glutamic acid, and carnitine. Guidelines indicate that 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 side effects such as sweating and diarrhea. Therefore, Sentra AM is not medically necessary.

**Gabadone #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 (Chronic) (1) Gabadone, (2) Medical Food.

**Decision rationale:** The claimant sustained a work-related injury in August 2008 and continues to be treated for chronic left shoulder pain. Gabadone is a medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. Guidelines recommend use of a medical food for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by a medical evaluation. In this case, there is no identified disease or condition that would indicate the need for a nutritional supplement and therefore, prescribing Gabadone is not medically necessary.