

<b>Case Number:</b>	CM14-0162437		
<b>Date Assigned:</b>	10/07/2014	<b>Date of Injury:</b>	02/06/1992
<b>Decision Date:</b>	11/07/2014	<b>UR Denial Date:</b>	09/02/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2014

### 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 Physical Medicine and Rehabilitation and is licensed to practice in Illinois. 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 injured worker is a 67-year-old female who reported an injury on 02/06/1992. The mechanism of injury was not provided. The injured worker has a diagnosis of myalgia and myositis, myofascial pain syndrome, cervicgia, headache, spasm of muscle, left shoulder impingement, right thumb and wrist arthrosis, and cervical sprain. Past medical treatment included medications. Diagnostic testing included a computerized tomography scan of the cervical spine on 09/09/2013. There was no pertinent surgical history. The injured worker complained of persistent left shoulder pain. The injured worker stated she gets a sharp pain in her shoulder when lifting up her arm. The injured worker stated since starting her medical foods Theramine, Sentra AM, and Sentra PM, she had been sleeping much better. The injured worker stated without medications, her pain would be a 9/10, and a 5/10 with medications. The physical examination revealed tenderness to palpation over the paracervical and trapezius muscles. The injured worker was able to move the neck, but only 15 degrees or less to the left, and 25 degrees to the right. Increased spasm of the shoulder and neck were noted, 5 trigger points noted, and bilateral tenderness and spasms of the cervical and trapezius muscles. There was abduction of left shoulder to 60 degrees, flexion 75 degrees, adduction 15 degrees, internal and external rotation at 25 degrees. There was a positive Neer's test of the left shoulder. Medications included Butrans, Flexeril, morphine sulfate, Medrox cream, Theramine, Sentra AM, Sentra PM, and Trepadone. The rationale for the request was not submitted. The treatment plan is for Sentra AM #60, Sentra PM #60, Theramine #90, and Trepadone #120. The Request for Authorization form was submitted on 09/04/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**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): Medical food

**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

**Decision rationale:** The request for Sentra AM #60 is not medically necessary. The injured worker complained of persistent left shoulder pain. The Official Disability Guidelines (ODG) states medical food (Sentra AM) is not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Additionally, the request does not indicate the frequency at which the medication is prescribed, the dosage of the medication, and the quantity of the medication being requested in order to determine the necessity of the medication. The guidelines do not support the request. Therefore the request for Sentra AM #60 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): Medical food

**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

**Decision rationale:** The request for Sentra PM #60 is not medically necessary. The injured worker complained of persistent left shoulder pain. The Official Disability Guidelines (ODG) states medical food (Sentra AM) is not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Sentra PM is a medical food from [REDACTED] intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan.

Additionally, the request does not indicate the frequency at which the medication is prescribed, the dosage of the medication, and the quantity of the medication being requested in order to determine the necessity of the medication. The guidelines do not support the request. Therefore the request for Sentra PM #60 is not medically necessary.

**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): Pain; Theramine

**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

**Decision rationale:** The request for Theramine #90 is not medically necessary. The injured worker complained of persistent left shoulder pain. The Official Disability Guidelines (ODG) state Theramine is not recommended for the treatment of chronic pain. Theramine is a medical food from [REDACTED], 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. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Additionally, the request does not indicate the frequency at which the medication is prescribed, the dosage of the medication, and the quantity of the medication being requested in order to determine the necessity of the medication. The guidelines do not support the request. Therefore the request for Theramine #90 is not medically necessary.

**Trepadone #120:** 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); Pain: Trepadone

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

**Decision rationale:** The request for Trepadone #120 is not medically necessary. The injured worker complained of persistent left shoulder pain. The Official Disability Guidelines (ODG) state Trepadone is not recommended for the treatment of chronic pain. Trepadone is a medical food from [REDACTED] that is a proprietary blend of L-

arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA). Additionally, the request does not indicate the frequency at which the medication is prescribed, the dosage of the medication, and the quantity of the medication being requested in order to determine the necessity of the medication. The guidelines do not support the request. Therefore the request for Trepadone #120 is not medically necessary.