

<b>Case Number:</b>	CM14-0111067		
<b>Date Assigned:</b>	08/01/2014	<b>Date of Injury:</b>	06/20/2008
<b>Decision Date:</b>	10/08/2014	<b>UR Denial Date:</b>	07/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/16/2014

### 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 & Rehabilitation 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:

The injured worker is a 58-year-old female who reported an injury on 06/20/2008. While working at the police department, she tripped and landed on her right hand and right knee, sustaining neck, back, shoulder, hip, knee, and ankle injuries. The injured worker had a history of lower back pain and neck pain. The injured worker had diagnoses of bilateral hip degeneration status post total hip replacement, right shoulder rotator cuff tear, bilateral shoulder impingement, bilateral knee degeneration, right knee tibial plateau fracture, cervical sprain, lumbar sprain, and upper extremity sprains. The past treatments included an electromyogram and an MRI. The medications included Norco, Neurontin, Ketoprofen cream, Flexeril, Sentra AM and Sentra PM, and Theramine. The physical examination of the right shoulder dated 06/15/2014 revealed abduction of 140 degrees to the right and 150 degrees to the left, flexion 150 to the right and 160 to the left, bilateral tenderness and spasm to the cervical and trapezius muscles, and increased bilateral tenderness and spasms to the L3-5 paraspinal muscles. The examination of the cervical spine revealed decreased range of motion of extension at 20 degrees and flexion at 40 degrees. Examination of the lumbar spine revealed decreased range of motion with extension of 10 degrees and flexion at 50 degrees. The motor examination was 5+ bilaterally to the upper extremities. The sensory examination revealed pinprick along the lateral anterior thigh. The treatment plan included Sentra AM, Sentra PM, and Theramine. The Request for Authorization dated 08/01/2014 was submitted with the documentation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra AM, Quantity 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-Treatment in Worker's Compensation Pain Procedure Summary

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: [www.ptlcentral.com](http://www.ptlcentral.com)

**Decision rationale:** The request for Sentra AM, quantity 60 is not medically necessary. The California MTUS/ACOEM and the Official Disability Guidelines did not address. Ptlcentral.com indicates that Sentra AM is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity induced fatigue syndrome, and impaired neurocognitive functions involving mental arousal, alertness, and memory. These conditions share an increased need for dietary Choline, Acetyl L Carnitine, and Glutamate to support neuromuscular, neuroendocrine, and neurocognitive functions dependent on Acetylcholine. Sentra AM is a medical food that must be used under the active or ongoing supervision of a physician. Medical foods are intended to address the different or altered physiologic requirements that may exist for individuals who have distinctive nutritional needs arising from metabolic disorders, chronic diseases, injuries, premature birth associated with inflammation and other medical conditions, as well as from pharmaceutical therapies. The clinical notes did not indicate that the injured worker had post-traumatic stress disorder or impaired neurocognitive functioning involving mental arousal, alertness, and memory. The request did not indicate the frequency or dosage. As such, the request is not medically necessary.

**Sentra PM, Quantity 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-Treatment in Worker's Compensation Pain Procedure Summary

**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, Quantity 60 is not medically necessary. The California MTUS/ACOEM did not address. The Official Disability Guidelines indicate that Sentra PM is a medical food from Targeted Medical Pharma Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression that is a proprietary blend of Choline Bitartrate, Glutamate, and 5 Hydroxytryptophan. The request did not address the dosage or frequency. As such, the request is not medically necessary.

**Theramine, Quantity 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-Treatment in Worker's Compensation Pain Procedure Summary

**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 Foods

**Decision rationale:** The request for Theramine, quantity 90 is not medically necessary. The California MTUS/ACOEM did not address. The Official Disability Guidelines state the definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) 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." To be considered, the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Per the clinical note, the injured worker did not require tube feeding or meet the criteria for a medical disorder, disease, or condition in which there are distinctive nutritional requirements. The request did not address the frequency and dosage. Theramine is not recommended. As such, the request is not medically necessary.