

Case Number:	CM14-0006333		
Date Assigned:	02/07/2014	Date of Injury:	05/10/2002
Decision Date:	07/18/2014	UR Denial Date:	01/08/2014
Priority:	Standard	Application Received:	01/16/2014

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 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:

The patient is a 62-year-old female who has submitted a claim for Post-cervical Laminotomy Pain Syndrome, Cervical Radiculitis, Fibromyalgia, Symptomatic Left Sacroiliitis, and history of Hepatitis C associated with an industrial injury date of May 10, 2002. Medical records from 2005 through 2014 were reviewed, which showed that the patient complained of neck pain with upper extremity radiating symptoms accompanied by numbness and weakness. She also complained of left hip and buttock pain. On physical examination, there was tenderness of the left sacroiliac joint sulcus. Left sacroiliac provocative test was positive. Gaenslen, Patrick, and sacroiliac thrust tests were also positive. Treatment to date has included medications, physical therapy, home exercise program, chiropractic care, cervical medial branch nerve blocks, left hip and left knee injections, cervical spine surgery, acupuncture, left shoulder arthroscopy, left sacroiliac joint intraarticular steroid injection, interferential unit, and medical food products including Sentra AM (since June 2013), Theramine (since October 2013), and GABAdone (since October 2013). Utilization review from January 8, 2014 denied the request for Sentra AM #60 because there were no patient indications that this medical food was a necessary part of the treatment regimen; Theramine #90 because of lack of guideline support for efficacy and safety; and GABAdone #60 because the documentation did not provide any specific medical diseases, disorders, or nutritional deficiencies that would necessitate the use of this medical food.

IMR ISSUES, DECISIONS AND RATIONALES

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

SENTRA AM #60 (DOSAGE UNKNOWN): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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: CA MTUS does not specifically address medical food. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines (ODG) was used instead. Sentra AM is a patented blend of neurotransmitters and neurotransmitter precursors (choline bitartrate and glutamate); activators of precursor utilization (acetyl-L-carnitine, glutamate, and cocoa powder); polyphenolic antioxidants (grapeseed extract, hawthorn berry, cocoa powder); an amino acid uptake stimulator (gingkgo biloba); an adenosine antagonist (cocoa powder); and an inhibitor of the attenuation of neurotransmitter production associated with precursor administration (grapeseed extract). ODG states that choline is a precursor of acetylcholine and 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. Regarding glutamate, ODG states that treatment indications for glutamic acid include those with impaired intestinal permeability, short bowel syndrome, cancer, and critical illness. In this case, Sentra AM was being prescribed since June 2013 (13 months to date). However, given the 2002 date of injury, the exact duration of use of this medical food product is not clear. The medical records stated that Sentra AM was recommended to be taken orally two capsules every morning before breakfast and it is a specially formulated medical food product for the dietary management of metabolic processes of fatigue and cognitive disorder. It was also reported that this medication helped restore energy levels and maintain activities of daily living in appropriate levels and results had been successful with the patient. However, the records failed to specify objective evidence of functional improvement with the use of Sentra AM. Furthermore, the above-mentioned conditions wherein choline and glutamate supplementation may be necessary, were not present in the patient. There is no clear indication for continued use of this medical food product. Therefore, the request for SENTRA AM #60 is not medically necessary.

THERAMINE #90 (DOSAGE UNKNOWN): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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[®], Medical Food.

Decision rationale: CA MTUS does not specifically address Theramine. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines (ODG) was used instead. ODG states that Theramine is not recommended. Theramine is a medical food product from Physician

Therapeutics, Los Angeles, California, 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. Regarding GABA, this supplement is indicated for epilepsy, spasticity, and tardive dyskinesia. Regarding choline, it is a precursor of acetylcholine and 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. Regarding L-arginine, this supplement is not indicated in current references for pain or inflammation but is indicated to detoxify urine. Regarding L-serine, there is no indication for the use of this supplement. In this case, Theramine was being prescribed since October 2013 (9 months to date). However, given the 2002 date of injury, the exact duration of Theramine use is not clear. The patient was diagnosed with fibromyalgia and the use of Theramine is intended for such condition but the medical records failed to provide objective evidence of functional benefits with the use of this medical food product. There is no clear indication for continued use Theramine at this time. Therefore, the request for THERAMINE #90 is not medically necessary.

GABADONE #60 (DOSAGE UNKNOWN): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: CA MTUS does not specifically address GABADone. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines (ODG) was used instead. ODG states that GABADone is not recommended. GABADone is a medical food product from Physician Therapeutics, Los Angeles, California, 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. Regarding choline, it is a precursor of acetylcholine and 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. Regarding glutamate, ODG states that treatment indications for glutamic acid include those with impaired intestinal permeability, short bowel syndrome, cancer, and critical illness. Regarding 5-hydroxytryptophan, this supplement has been found to possibly be effective in the treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders and has been found to be effective for depression. Regarding GABA, this supplement is indicated for epilepsy, spasticity, and tardive dyskinesia. In this case, GABADone was being prescribed since October 2013 (9 months to date). However, given the 2002 date of injury, the exact duration of GABADone use is not clear. Furthermore, the medical records failed to provide objective evidence of functional gains. Moreover, although the patient was diagnosed with fibromyalgia and was noted to have previous sleep difficulties wherein supplementation may be appropriate,

there was no discussion regarding the indication for prescribing GABAdone. Therefore, the request for GABADONE #60 is not medically necessary.