

Case Number:	CM14-0048354		
Date Assigned:	07/02/2014	Date of Injury:	01/21/1997
Decision Date:	08/21/2014	UR Denial Date:	04/01/2014
Priority:	Standard	Application Received:	04/04/2014

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 52-year-old male who has submitted a claim for chronic low back pain, and lumbar radiculopathy; associated with an industrial injury date of 01/21/1997. Medical records from 2013 to 2014 were reviewed and showed that patient complained of back spasms. Physical examination showed bilateral tenderness and spasms of the L3-L5 and L5-S1 paraspinous muscles and bilateral sacroiliac joints. Range of motion of the cervical spine was decreased. FABER sign was positive. Sensation was decreased over the left lateral leg and right posterior leg. Patient was unable to balance on the left leg. MRI of the lumbar spine, dated 08/18/2010, showed multiple disc bulges at L3-L4 and L4-L5. Bone scan, dated 08/11/2010, showed no abnormality of spine and knees, and an old 8th rib fracture. Treatment to date has included medications, physical therapy, and home exercise program. Utilization review, dated 04/01/2014, denied the request for Theramine because there was no objective evidence to support the medical necessity of the medical food for the treatment of the provided diagnosis; and denied the request for Sentra AM because the medical food is not FDA-approved, there was no documented failure of the many sleep remedies available OTC, and there was no demonstrated medical necessity for the continuation of a sleep aid 17 years after the DOI.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medication Page(s): 22,67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)-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, Theramine.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. According to ODG, Theramine is not recommended. It is a medical food that is a proprietary blend of GABA and choline bitartrate, L-arginine, and L-serine intended for management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Regarding GABA, there is no high quality peer-reviewed literature that suggests that GABA is indicated. Regarding choline, there is no known medical need for supplementation. Regarding L-Arginine, this medication is not indicated in current references for pain or inflammation. Regarding L-Serine, there is no indication for the use of this product. In this case, patient was prescribed Theramine since at least March 2014. However, guidelines do not support the use of Theramin. Lastly, the present request as submitted failed to specify the number to be dispensed. Therefore, the request for THERAMINE #90 is not medically necessary.

Sentra (Strazepam) AM #60 with two refills: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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 at least March 2014. The medical records stated that Sentra AM was prescribed to help with alertness and energy, and patient was able to discontinue Tylenol.

However, 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 (STRAZEPAM) AM #60 WITH 2 REFILLS is not medically necessary.