

Case Number:	CM14-0008484		
Date Assigned:	02/12/2014	Date of Injury:	04/24/2008
Decision Date:	07/02/2014	UR Denial Date:	12/19/2013
Priority:	Standard	Application Received:	01/21/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a Physician Reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The Physician 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 Physician 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 23-year-old male who has filed a claim for lumbar disc protrusion and stenosis associated with an industrial injury date of April 24, 2008. Review of progress notes indicates constant low back pain, and relief with medications. Findings include decreased lumbar range of motion, tenderness of the lumbar spine with spasms, and difficulty performing heel/toe walking. Patient experienced difficulty sleeping due to persistent low back pain. Treatment to date has included NSAIDs, opioids, and sedatives. Utilization review from December 19, 2013 denied the request for Theramine #60, Sentra AM #60, Sentra PM #60, and Gabadone #60 as these medical foods are not supported in the guidelines.

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 (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress chapter, Theramine.

Decision rationale: The California MTUS does not address this topic. According to 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. There is no documented rationale for this request. There is also no evidence of prior use of this medication. In this case, there is no need for variance from the guidelines. Therefore, the request for Theramine #60 was 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 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 Chapter, Medical Food Section X Other Medical Treatment Guideline or Medical Evidence http://www.ptlcentral.com/downloads/monographs/Sentra_AM_latest.pdf.

Decision rationale: The California MTUS does not address this topic. According to the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines (ODG) Pain Chapter, Medical Food Section was used instead. The ODG indicates that medical foods are dietary management for a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. An online search showed that Sentra AM is a medical food that 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. In this case, there is no documentation that this employee has the above-mentioned conditions. Documentation does not provide the rationale for this request, or of any nutritional deficiencies in this employee. Therefore, the request for Sentra AM #60 was 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 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 chapter, Sentra PM.

Decision rationale: The California MTUS does not address this topic. According to the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. According to ODG, Sentra PM is intended for use in management of sleep disorders associated with depression. Sentra PM is a proprietary blend of choline, bitartrate, glutamate, and 5-hydroxytryptophan. 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. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, there is no indication regarding the rationale for this request. The employee's sleep difficulty is reported to be due to the persistent low back pain, and not due to a circadian rhythm disorder. There is also no documentation regarding nutritional deficiencies in this employee. Therefore, the request for Sentra PM #60 was 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 (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 chapter, GABAdone.

Decision rationale: The California MTUS does not address this topic. According to the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. The Official Disability Guidelines also indicate that GABAdone is not recommended as it is a medical food. It 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. There is no documentation regarding nutritional deficiencies in this employee, or of the conditions as mentioned above. Also, this compound is not recommended for use. Therefore, the request for Gabadone #60 was not medically necessary.