

Case Number:	CM14-0080179		
Date Assigned:	09/18/2014	Date of Injury:	08/04/2012
Decision Date:	10/16/2014	UR Denial Date:	05/13/2014
Priority:	Standard	Application Received:	05/30/2014

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 Geriatrics and is licensed to practice in New York. 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 man with a date of injury of 8/4/12. He was seen by his pain management physician on 4/18/14. He was using ibuprofen for pain management. His exam showed significant tenderness over the anterior part of the subacromial space and biceps tendon of right shoulder with painful range of motion. Yergason's test was positive. He had slight tenderness over the distal biceps tendon and medial epicondyle. His diagnoses were bicep tenosynovitis and impingement syndrome, right shoulder and biceps tendinitis and medial epicondylitis, right elbow. He had received acupuncture in the past. At issue in this review is the request for sentra pm and theramine. Length of prior therapy is not documented.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra PM #60: 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 Other Medical Treatment Guideline or Medical Evidence: Uptodate: treatment of insomnia http://nutrientpharmacology.com/sentra_AM.html and

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

Decision rationale: Sentra pm is a medication food. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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." The records do not substantiate why a medical food is being used instead of or in addition to traditional medications. Patients with insomnia should receive therapy for any medical condition, psychiatric illness, substance abuse, or sleep disorder that may cause or worsen the problem and receive advice regarding sleep hygiene. After this, cognitive behavioral therapy would be trialed first prior to medications. In this injured worker, his sleep pattern, hygiene or level of insomnia is not addressed. The documentation does not support the medical necessity for sentra pm.

Theramine #90: 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 Other Medical Treatment Guideline or Medical Evidence: FDA website:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

Decision rationale: Theramine is medical food used to treat chronic pain syndromes and low back pain. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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." The records do not substantiate why a medical food is being used instead of or in addition to traditional medications. The medical necessity for theramine is not documented.