

Case Number:	CM14-0173752		
Date Assigned:	10/27/2014	Date of Injury:	05/31/2009
Decision Date:	12/04/2014	UR Denial Date:	09/22/2014
Priority:	Standard	Application Received:	10/21/2014

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 Family 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:

This is a 24-year-old female patient who reported an industrial injury on 5/31/2009, over five (5) years ago, attributed to the performance of her usual and customary job tasks. The patient complained of neck, shoulder, and upper back pain. The objective findings on examination included tenderness to the lower and upper paravertebral cervical spine musculature; mild restriction in range of motion of the cervical spine. The diagnoses included "type I" diabetes mellitus; unspecified diabetic retinopathy with macular edema; PTSD; and insomnia. The patient was prescribed Sentra AM.

IMR ISSUES, DECISIONS AND RATIONALES

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

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, Medical food

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant

health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food Sentra AM, is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. There was no substantive objective evidence provided by to support the medical necessity of a medical food, such as, Sentra AM over the medications readily available over the counter for similar purposes. There is no demonstrated medical necessity for the requested Sentra AM for the treatment of the effects of the reported industrial injury. The prescription of the medical food Sentra AM (Strazepam) as a medical food is not recommended by the ACOEM Guidelines or the Official Disability Guidelines for the treatment of insomnia or a sleep disorder. The prescribed Sentra AM was not demonstrated to be medically necessary. It is not clear that the patient is diagnosed with a sleep disorder or experiences occasional insomnia. There is no medical necessity for the prescription of Sentra AM for the patient. There is no documented evidence that the patient has failed the use of the numerous available sleep aids over-the-counter. The request for the authorization of Sentra AM is not supported with objective medically based evidence. There is no medical necessity for the medical food Sentra AM for the effects of the industrial injury. There is no evidence that this prescribed medical food provides functional improvement or even helps with sleep. The prescription of medical foods is not recommended by the CA MTUS or the Official Disability Guidelines. The use of the medical food is not supported with clinical evidence or supported with objective peer-reviewed evidence. The medical foods prescribed in addition to the oral medications prescribed are not demonstrated to be medically necessary. Sentra AM was prescribed for sleep. The medical food is prescribed routinely for sleep and not on a prn basis. The medical food is not FDA approved. There is no documented failure of the many sleep remedies available OTC. There is no demonstrated medical necessity for the continuation of a sleep aid five (5) years after the DOI. There is no medical necessity for a medical food for increased energy with AM or PM formulations. Therefore, the request is not medically necessary.