

Case Number:	CM13-0019914		
Date Assigned:	10/11/2013	Date of Injury:	11/06/1996
Decision Date:	02/03/2014	UR Denial Date:	09/05/2013
Priority:	Standard	Application Received:	09/06/2013

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 Emergency Medicine, and is licensed to practice in <MPR ST LICENSE>. 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.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

Patient is a 72 year old female with date of injury on 11/6/1996. Report of left leg, left hip and lower back injury after "struck left thigh on warmer". Has a diagnosis of lumbar disc disorder. There are several notes that mention that patient's neck pains are not related to the industrial injury. Patient reports 9/10 pain on neck and low back radiating to right leg and foot that is preventing her from sleeping. Chart on 7/31/13 by [REDACTED] (Physician Assistant with [REDACTED]) reports that the patient has chronic neck and lower back pains radiating to her right leg, pain reported at 9/10 affecting both shoulders radiating down both arms and low back radiating down both legs. Chart on 9/25/13 by [REDACTED] (Physician Assistant with [REDACTED]) reports that the patient was complaining of sharp and constant pains (No severity or location noted), and difficulty sleeping with pain. Objective findings of antalgic gait using cane. Lumbar paravertebral muscle spasms bilaterally with positive straight leg raise on the right. Also notes mild weakness on right leg. There is no recent MRI available. Note from 9/25/13 recommended an MRI of her lumbar spine. Patient is currently on Prevacid, Xanax, Soma, MS Contin, Norco and Rozerum. Patient has chronically been on these medications, but there is no documentation of how long. Request is for review of Sentra PM (290/40/15/70) prescribed by [REDACTED] (Pain management) for undefined sleep disturbances. A letter by [REDACTED] (neurology) on 11/11/09 states there was a request for Sentra PM by [REDACTED] at that time but did not recommend it due to lack of evidence. Utilization review on 9/5/13 recommend non-certification.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra PM 290/40/15/70mg #120: 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), Sentra PM.

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, and website http://tmedpharma.com/docs/monographs-10-09/Sentra_PM_Monograph_v_Final_10-15-2009.pdf.

Decision rationale: Sentra PM is an herbal supplement marketed as a "medical food" containing Choline Bitartrate, Glutamic Acid, 5-hydroxytryptophan, Acetyl L-Carnitine, Ginkgo Biloba, Griffonia Extract (5HTP 95%), Hawthorn Berry and Cocoa. It is marketed as a sleep aid for people with "nutritional deficiencies associated with sleep disorders." Patient's doctor has prescribed it for sleep management and not for pain. The ODG indicates medical food is defined as "a food which is formulated to be consumed or internally 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." ODG reviews the evidence for each component of Sentra PM for insomnia and concludes that all components have little to no evidence for use in insomnia except for some poor evidence of of insomnia improvement in 5-hydroxytryptophan. Documentation states that patient has a hard time sleeping due to pain but there is no details as to the severity of the sleep problem or any significant deficiencies or disability from it. There is no information of other attempted treatments for the sleep problem although patient is already on Xanax and Rozerum both of which are sleep medications. There is no record of any sleep studies. Patient has no documented nutritional deficiency causing insomnia. Documentation reports that patient's insomnia is primarily due to pain therefore a "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Sentra PM is not recommended.