

Case Number:	CM13-0037428		
Date Assigned:	12/13/2013	Date of Injury:	05/25/2012
Decision Date:	02/11/2014	UR Denial Date:	10/08/2013
Priority:	Standard	Application Received:	10/23/2013

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 Psychiatry 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:

This case involves a 41 year old female who sustained a slip and fall injury on May 25, 2012. The patient has been treated with norco, progesterone, prilosec and naproxen. The patient has had sharp burning back pain which is made worse by extended sitting as well as increased activity. The patient has been depressed and anxious because her back pain has not improved. An MRI on July 24, 2013 showed bulging discs in the lumbar region as well as sacroiliac joint inflammation. The issue at hand is whether Sentra PM, a medical food, is medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro sentra PM for lumbar spine pain and psyche: Upheld

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

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 and stress chapter, section on Sentra PM

Decision rationale: The CA MTUS is silent on Sentra PM. The Official Disability Guidelines (ODG) Mental Illness and stress chapter, Section on Sentra PM, which has the following to state about Sentra PM: "Under study for insomnia. Preliminary results are promising, from a single

study sponsored by the manufacturer, but independent unbiased studies are necessary for a recommendation. Sentra PM[®] is a medical food from Targeted Medical Pharma (aka Physician Therapeutics), Los Angeles, CA, intended for use in management of sleep disorders, which is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. In a RCT published in a pay-to-publish journal, and written by employees of the marketer of Sentra PM, the authors concluded that Sentra PM can improve the quality of sleep, the response to trazodone as a sleep medication and parasympathetic autonomic nervous system activity. (Shell, 2012) See also Insomnia treatment, where it says there is limited evidence to support trazodone for insomnia, but it may be an option in patients with coexisting depression. See also Sentra PM[®] in the Pain Chapter." The Psychiatric consult from 9-27-13 by [REDACTED] states, "Medications: Norco, naproxen, Prilosec, Zanaflex, and fiber. She was on Xanax for one weekend. She is using senna. The claimant is on Sentra PM which is not helping. She is using an average of five tablets of Norco per day. She is using Zanaflex on average three tablets a day." Sentra PM is a medical food. This patient has had extended exposure to both prescription opiates and benzodiazepines. Optimally the use of these drugs should be limited over time. Sentra PM is a medical food. Though prescription, it is not a controlled substance. The guidelines use the word "promising", and the use of this drug seems reasonable and therefore medically necessary. The problem with the wording of this request is that there was not endpoint or limit to the request the way it was worded when received by this reviewer. Though use of Sentra PM seems appropriate per guidelines, unlimited use of this or any medicine is not medically necessary.