

Case Number:	CM15-0081753		
Date Assigned:	05/04/2015	Date of Injury:	01/29/2013
Decision Date:	06/05/2015	UR Denial Date:	04/17/2015
Priority:	Standard	Application Received:	04/28/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: New Jersey, New York
 Certification(s)/Specialty: Family Practice

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 60-year-old female, who sustained an industrial injury on 1/29/13. She reported injury to legs, ankles and feet. The injured worker was diagnosed as having cervical spine sprain/strain, cervical radiculopathy, lumbar radiculopathy, lumbar spine disc protrusion, lumbar spondylosis, bilateral knee sprain/strain, left ankle tenosynovitis, right plantar fasciitis and right calcaneal spur. Treatment to date has included oral medications including opioids, topical medications, intramuscular injections, acupuncture and physical therapy. Currently, the injured worker complains of constant low back pain radiating to lower extremities with numbness and tingling rated 8/10, constant bilateral knee pain rated 7/10 and constant bilateral ankle/feet pain rated 8/10. Physical exam noted tenderness to palpation along the cervical spine and tender and spasms along the trapezius muscles on the right, tender to palpation along the lumbar spine and along the paravertebral muscles bilaterally with palpable spasms along the paravertebral muscles of lumbar spine bilaterally, tenderness along lateral joint bilaterally of right knee and restricted range of motion of left and right ankles. The treatment plan included prescriptions for Theramine, Sentra, Gabadone, Tramadol and Zofran.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zofran 4 mg #30: 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), pain chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Antiemetics.

Decision rationale: The request is not considered medically necessary. MTUS does not address the use of Ondansetron (Zofran). According to ODG guidelines, ondansetron is not recommended for nausea and vomiting due to chronic opioid analgesics. This medication is used for nausea associated with chemotherapy, treating cancer pain, or post-operative pain. The patient is not being treated with chemotherapy, for cancer pain, or post-operative pain and is using it for opioid-induced nausea. Therefore, she will not need Ondansetron and the request is considered 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), mental and stress chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) <Pain<Medical FoodFDA section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

Decision rationale: Sentra PM is a medical food that is used for sleep disorders associated with depression. The ingredients include neurotransmitter precursors (choline bitartrate, glutamate, and 5-hydroxytryptophan); polyphenolic antioxidants (hawthorn berry, cocoa); an amino acid uptake stimulator (gingko biloba); activators of amino acid utilization (acetyl-L-carnitine, glutamate, cocoa powder); and an adenosine antagonist (cocoa powder). The FDA defines medical food in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "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." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Sentra PM does not meet the requirement for medical food as stated by the FDA. There is no documented nutritional deficiency for which a medical food is required. For the patient, there is no documentation of sleep disorders or depression, as well as a documented discussion of proper sleep hygiene. Therefore, Sentra PM is not considered medically necessary.

