

Case Number:	CM14-0029500		
Date Assigned:	03/19/2014	Date of Injury:	02/04/2005
Decision Date:	04/25/2014	UR Denial Date:	02/28/2014
Priority:	Standard	Application Received:	03/08/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Interventional Spine 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:

The patient is a 65 year old male with date of injury of 02/04/2005. The listed diagnoses per [REDACTED] are Status post esophagogastroduodenoscopy with biopsy, 11/27/2013; Cervical spine multilevel spondylosis with severe bilateral neuroforaminal narrowing C4-C5, C5-C6 and C6-C7; Lateral epicondylitis; Right shoulder impingement and radiation of pain from the neck to the right shoulder; Constipation; Acid reflux; and sleep disorder. The progress report dated 08/08/2013 by [REDACTED] shows that the patient complains of neck pain radiating into his right hand. The physical exam shows neck stiffness, spasms and radiating symptoms to the right. No other significant findings were reported. The treating physician is requesting Sentra AM, Sentra PM and Theramine.

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 (ODG) Medical Foods

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

Decision rationale: The MTUS and ACOEM guidelines are silent when it comes to this product. The Official Disability Guidelines (ODG) on medical food states that for Choline, state, "There is no known medical need for choline supplementation." MTUS also states that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, choline, and ingredient in Sentra is not supported by ODG guidelines. The request for Sentra AM # 60 is not medically necessary and appropriate.

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) Medical Foods

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

Decision rationale: The Official Disability Guidelines (ODG) states that, "Sentra PM is a medical food from Targeted Medical Pharma Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan." ODG further states that for each ingredient: for choline, "There is no known medical need for choline supplementation"; for Glutamic Acid, "This supplement is used for treatment of hypochlorhydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine."; for 5-hydroxytryptophan, "This supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression." MTUS also states that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, choline, and ingredient in Sentra PM is not supported by ODG guidelines. The request for Sentra PM # 60 is not medically necessary and appropriate.

THERAMINE #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)

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

Decision rationale: The patient presents with constipation and acid reflux. He is status post esophagogastroduodenoscopy with biopsy from 11/27/2013. The MTUS and ACOEM guidelines are silent with regards to this product. However, the Official Disability Guidelines (ODG) state that Theramine is a proprietary medication of Physician Therapeutics based in [REDACTED]. Its intended use is in the management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. ODG further states that for GABA,

"There is no high quality peer-reviewed literature that suggests that GABA is indicated." Secondly, for Choline, "There is no known medical need for choline supplementation." Thirdly, for L-Arginine, "This medication is not indicated in current references for pain or inflammation." Lastly for L-Serine, "There is no indication for the use of this product." The request for Theramine # 60 is not medically necessary and appropriate.