

Case Number:	CM14-0211099		
Date Assigned:	12/23/2014	Date of Injury:	02/18/2005
Decision Date:	02/19/2015	UR Denial Date:	11/18/2014
Priority:	Standard	Application Received:	12/16/2014

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. 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, Michigan, California
 Certification(s)/Specialty: Neurology, Neuromuscular Medicine

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 50-year-old woman who sustained a work-related injury on February 18, 2005. Subsequently, she developed chronic neck and shoulder pain. The patient underwent ACDF at C5-6 on January 26, 2006; thoracic outlet syndrome surgery, transaxillary first rib resection, lysis and release of subclavian artery and vein, and neurolysis of the brachial plexus on July 7, 2008; redo neurolysis of the brachial plexus, right sided lysis of adhesions, supraclavicular scalenectomy on November 11, 2009; and ACDF at C4-5 and C6-7 on November 1, 2012. A visit report dated July 22, 2014 documented that the patient was still on a lot of pain medications. She was diagnosed with hypertension, constipation, and acute gastritis. According to the progress report dated October 21, 2014, the patient had no real change in left arm pain from both sides, mostly left. They were talk about surgery. The patient did not want the surgery that they were recommending but she would like physical therapy and smaller surgery. The provider requested authorization for Theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #90: 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; Theramine

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) <http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Medicalfood>.

Decision rationale: According to ODG guidelines, medical food. < Recommended as indicated below. Definition: Defined 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 entirely 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. See Food labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule (56 FR 60366 at 60377, November 27, 1991). Medical foods are exempted from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343 (q) (5) (A) (iv)). Medical foods do not have to be registered with the FDA. (CFSAN, 2008) Current available medical food products: Choline: Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. (AltMedDex, 2008) (Clinical Pharmacology, 2008)Glutamic Acid: This supplement is used for treatment of hypochlohydria 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. (AltMedDex, 2008) (Lexi-Comp, 2008) 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. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. (De Benedittis, 1985) (Klarskov, 2003) (AltMedDex, 2008) (Lexi-Comp, 2008)Gamma-aminobutyric acid (GABA): This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety. Dose reductions are indicated for a creatinine clearance > 60 ml/min. (AltMedDex, 2008) In this low quality RCT, with no description for the actual sleep disorder, an amino acid preparation containing both GABA and 5-hydroxytryptophan reduced time to fall asleep, decreased sleep

latency, increased the duration of sleep, and improved quality of sleep. (Shell, 2009)L-Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement.L-Arginine: This supplement is not indicated in current references for pain or "inflammation." It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome. (AltMedDex, 2008) (CFSAN, 2008) (Clinical Pharmacology, 2008) (Lexi-Comp, 2008) (Micromedex, 2008)Honey & cinnamon: Recommended as an option for arthritis pain. See separate listing for Honey & cinnamon.Limbrel (flavocoxid): Under study as an option for arthritis in patients at risk of adverse effects from NSAIDs, with recent evidence that Limbrel is capable of causing acute liver injury and should be used with caution. (Chalasan, 2012) See separate listing for Limbrel (flavocoxid/ arachidonic acid). See also NSAIDs, GI symptoms & cardiovascular risk; & NSAIDs, hypertension and renal function.See also Compound drugs; Co-pack drugs; Physician-dispensed drugs; Repackaged drugs. For brand names of medical foods and their respective ingredients, see Deplin (L-methylfolate); GABAdone; Sentra PM ; Theramine; Trepadone; & UltraClear>. There are no controlled studies supporting the safety and efficacy for the use of Theramine for the treatment of pain. Furthermore, there no documentation that the patient suffered from a nutrition deficit that requires the use of Theramine. Based on the above, the prescription of Theramine #90 is not medically necessary.