

Case Number:	CM13-0043703		
Date Assigned:	12/27/2013	Date of Injury:	10/31/2012
Decision Date:	02/28/2014	UR Denial Date:	10/10/2013
Priority:	Standard	Application Received:	10/24/2013

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 New York and Tennessee. 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:

Medical records are limited. The patient is a male who was experiencing continuing right knee pain post surgically. Date of injury was October 31, 2012. Request for Therapfen-800 was submitted on October 8, 2013.

IMR ISSUES, DECISIONS AND RATIONALES

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

Therapfen 800 (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).

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

Decision rationale: Theramine® is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Medical Food is a food which is formulated to be consumed or administered 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. GABA is indicated for epilepsy, spasticity and tardive dyskinesia. There is no documentation that any of these conditions is present in the patient. 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. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). There is no indication for the use of serine. Arginine is not indicated in current references for pain or inflammation. Theramine is not recommended under ODG.