

Case Number:	CM13-0024540		
Date Assigned:	12/11/2013	Date of Injury:	02/02/2010
Decision Date:	02/13/2014	UR Denial Date:	08/29/2013
Priority:	Standard	Application Received:	09/16/2013

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 Internal Medicine and is licensed to practice in New York. 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:

The patient is a 46 year old male with a history of injury 2/2/10. He has a history of anterior cervical fusion C5-6, C6-7, with radiculopathy, history of right shoulder injury and repair, right knee operation and carpal tunnel syndrome. He has complaints of right shoulder, neck, hand and knee pain. Patient is on hydrocodone and an anti-inflammatory. On 6/28/13, he was prescribed theramine. On 8/29/13, utilization review did not certify this medication. An appeal was made 9/11/13.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine 450mg: 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: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Web MD, FDA section 5(b) of the orphan drug act (21 U.s.c.360ee (b) (3)).

Decision rationale: The MTUS, ACOEM and WebMD are silent on medical foods. Neither theramine nor any other medical food is recommended for any condition. FDA Definition: of medical foods Defined in 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. The record does not indicate any specific dietary deficiencies that the patient needs treatment for. The thiamine remains noncertified.