

Case Number:	CM13-0066191		
Date Assigned:	01/03/2014	Date of Injury:	04/01/2011
Decision Date:	03/26/2014	UR Denial Date:	11/22/2013
Priority:	Standard	Application Received:	12/16/2013

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 Geriatrics, 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 injured worker is a 49 year old man with a date of injury of 4/1/11. He was seen by his primary treating physician on 10/29/13 for complaints of severe left and right knee pain and intermittent, moderate low back pain and right ankle pain. He requested refill of medications and he was working 'mod duty'. He has had various radiologic studies and his diagnoses included left knee grade III medial meniscal tear with 1 cm Baker's cyst, right thigh contusion with right leg causalgia and right knee internal derangement, right ankle pain with effusion, lumbar radiculopathy with spondylosis and sleep and depressive disorder. The treatment plan was to refill oral and transdermal medications, consult outpatient orthopedist and custom orthotics. At issue in this review is the refill of theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine Tablets #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- Treatment of workers' Compensation (ODG-TWC), Online Edition, Pain Chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA website:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods>

Decision rationale: Theramine is medical food used to treat chronic pain syndromes and low back pain. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. The medical necessity for theramine is not documented. Therefore, Decision for Theramine Tablets #60 is not medically necessary and appropriate.