

Case Number:	CM14-0068506		
Date Assigned:	07/14/2014	Date of Injury:	01/20/2009
Decision Date:	09/10/2014	UR Denial Date:	05/06/2014
Priority:	Standard	Application Received:	05/13/2014

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 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 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 injured worker is a 39 year old man with a date of injury of 1/20/09. He was seen by his primary treating physician on 2/25/14 with lumbar spine and right hip/knee pain. He was receiving physical therapy and using an H wave and TENS unit. He reported falls due to his legs giving out. His medications included Gabapentin, Butrans, Meloxicam, Prilosec, Cymbalta, Theramine, Soma, Ambien and Lidoderm patches. His physical exam showed pain with palpation in the right knee with extension to 120 degrees and flexion to 125 degrees. He had pain with right compression and external rotation in both hips. His left knee had pain on palpation of the anterior tibia consistent with a recent contusion. His lumbar spine exam showed absent lower extremity reflexes and weakness in L3-4 myotomes with decreased sensation in L5-S1 dermatomes. His diagnoses were chronic pain syndrome, LS spine DDD and radiculitis, OA hip and sprain/rupture of medial collateral ligament and obesity. At issue in this review is the refill of Theramine. Length of prior prescription is not documented in the note.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE REQUEST FOR THERAMINE FOR THE LOW BACK, RIGHT HIP AND RIGHT KNEE DOS 2/25/14: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:

<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 in pain or function with this medication or why a medical food is being used instead of or in addition to traditional medications. The medical necessity for Theramine is not documented.