

Case Number:	CM14-0150534		
Date Assigned:	09/18/2014	Date of Injury:	05/18/2006
Decision Date:	10/16/2014	UR Denial Date:	08/15/2014
Priority:	Standard	Application Received:	09/08/2014

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 Occupational Medicine and is licensed to practice in California. 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 70 year-old male with date of injury 05/18/2006. The medical document associated with the request for authorization, a primary treating physician's progress report, dated 07/22/2014, lists subjective complaints as low back pain with radicular symptoms down both legs and bilateral knees. Objective findings include an examination of the lumbar spine which revealed restricted range of motion in all planes secondary to pain. Tenderness to palpation of the paravertebral muscles with spasms and straight leg raises positive bilaterally. Bilateral knee range of motion with crepitus was reduced. Diagnoses are lumbar radiculitis, lumbar disc protrusion, bilateral knee internal derangement and bilateral knee OA. The medical records supplied for review document that the patient had first been prescribed Theramine 30mg, #90 and Trepadone, #120 on 01/27/2014, but the request was non-certified. Medications: 1. Theramine 30mg, #90 2. Trepadone, #120 No SIG provided for the above medications.

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) Pain (Chronic), Medical food

Decision rationale: Theramine is a medical food that is that to promote the production of the neurotransmitters that help manage and improve the sensory response to pain and inflammation. Medical food is 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 internally 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. Medical foods do not have to be registered with the Food and Drug Administration (FDA) and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. No high quality studies exist for Theramine. The Official Disability Guidelines (ODG) does not support the use of Theramine; therefore, this request is not medically necessary.

Trepadone, #120: 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, Medical Foods; Thepadone

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

Decision rationale: Trepadone is a medical food intended for use in the management of joint disorders. Medical food is 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 internally 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. The Official Disability Guidelines (ODG) does not support the use of Trepadone; therefore, this request is not medically necessary.