MAXIMUS Federal Services

Case Number:	CM14-0125162		
Date Assigned:	09/16/2014	Date of Injury:	10/08/2002
Decision Date:	11/17/2014	UR Denial Date:	07/22/2014
Priority:	Standard	Application Received:	08/07/2014

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 Internal 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 is a 57-year-old female whose date of industrial injury was 10/08/2002. She was seen on 5/30/2014. She was complaining of low back pain. On examination, the patient's gait was antalgic and she had worsening of gait related pain with heel to toe walking. There was limited range of lumbar spine motion. The right L4 and L5 dermatome and left L4 dermatome were with diminished sensation. Minor weakness in the toe extensors of the left and knee extensors on the left and right was noted. Diagnoses included lumbar spine surgery in 2006, lumbar disc disease, radiculopathy, and arthropathy. She was status post ankle open reduction and internal fixation. The patient was on Oxycontin, Percocet, Lyrica, and Prilosec. Clinical note from February 2014 was virtually identical to the clinical note from May 2014.

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: Decision based on MTUS ACOEM Chapter 13 Knee Complaints. Decision based on Non-MTUS Citation Pub Med Search And Harrison Textbook Of Medicine, Work Loss Data Institute, Official Disabilities Guidelines Treatment in Workers Compensation, 7th Edition 2010: Pain (Chronic); Theramine Capsules (Medical Food)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental

Medicine (ACOEM), 2nd Edition, (2004) Chronic Pain, page(s) 136-137; Other Medical Treatment Guideline or Medical Evidence

Decision rationale: There are no high quality studies to attest to the efficacy of Theramine in the peer-reviewed literature. Other standard therapies need to be applied first, before resorting to a regimen that has minimal evidence base to support it. Therefore, the request is not recommended. There are only two studies of Theramine, both sponsored and conducted by the manufacturer, using low dose Ibuprofen against the product. These results have not been replicated by any other group. There is significant conflict of interest of the primary author and other authors, therefore the results are not robust.