

<b>Case Number:</b>	CM13-0067842		
<b>Date Assigned:</b>	06/23/2014	<b>Date of Injury:</b>	02/21/2013
<b>Decision Date:</b>	08/06/2014	<b>UR Denial Date:</b>	12/13/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/18/2013

### 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 patient is a 60 year-old male with date of injury 02/21/2013. The primary treating physician's progress report, dated 08/16/2013, lists subjective complaint as pain the bilateral shoulders. He has been treated with physical therapy and medications, but reports no significant relief from his symptoms. Objective findings include examination of the bilateral shoulders which revealed tenderness to palpation over both greater tuberosities and slightly over both acromioclavicular joints. Range of motion was decreased due to pain. Markedly positive impingement tests bilaterally and markedly positive O'Brien's test. Diagnoses include degenerative joint disease, left shoulder ; and degenerative joint disease, right shoulder. The medical records provided for review document that the requested medication is a new prescription. Medications: Theramine 450mg #180, No SIG given.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective request for Theramine 450 MG # 180 date of service 08/15/13.:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Work Loss Data Institute, Official Dissability Guidelines, pain (chronic), updated 11-14-2013.

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

**Decision rationale:** Theramine is a Food and Drug Administration regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. 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 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. Medical foods are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Therefore, the retrospective request for Theramine 450 mg# 180 date of service 08/15/13 is not medically necessary and appropriate.