

<b>Case Number:</b>	CM15-0062153		
<b>Date Assigned:</b>	04/08/2015	<b>Date of Injury:</b>	04/28/2012
<b>Decision Date:</b>	05/07/2015	<b>UR Denial Date:</b>	02/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/01/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Emergency Medicine

### 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 57 year old female, who sustained an industrial injury on April 28, 2012. The injured worker was diagnosed as having chronic low back pain and lumbar radiculopathy affecting the left L5 and S1 nerve roots. Treatment to date has included lumbar spine MRI, physical therapy, and medication. Currently, the injured worker complains of lower back pain that radiates to the back and left lower extremity. The Primary Treating Physician's report dated February 27, 2015, noted the injured worker reporting a flare-up of pain due to lack of medications. Physical examination was noted to show pain with anterior lumbar flexion, and extension, with straight leg raise positive on the right. The treatment plan was noted to include continuation of Vicodin, waiting authorization for a lumbar epidural steroid injection (ESI) and lumbar brace, and prescription for Theramine to reduce pain and inflammation affecting her back and to replace or reduce non-steroid anti-inflammatory drugs (NSAIDs) use.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Theramine #90, DOS: 2/27/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG: Pain Chapter, Theramine.

**Decision rationale:** Theramine is a brand name product, being sold by [REDACTED], containing multiple non-prescription generic substances including "amino acids and polyphenol ingredients" claimed by its manufacturer to aid in various "inflammatory conditions" and pains. There is only marketing information available online. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. There is no corresponding sections in ACOEM or MTUS concerning these substances. The ODG indicates medical food is defined as "a food which is formulated to be consumed or 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." ODG reviewed each individual component in Theramine and found no evidence to support its use and does not recommend the use of Theramine. ODG reviewed 2 studies supported by the manufacturer and found the studies to be deeply flawed with no possible conclusion could be drawn by such poor studies. Patient has no documented nutritional deficiency causing pain. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Theramine is an unevidenced non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.