

<b>Case Number:</b>	CM14-0104340		
<b>Date Assigned:</b>	09/16/2014	<b>Date of Injury:</b>	09/21/2007
<b>Decision Date:</b>	11/28/2014	<b>UR Denial Date:</b>	06/17/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/07/2014

### 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 in Family 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:

This 59-year old packer reported injuries to his neck, low back and bilateral upper extremities as a result of a fall at work, date of injury 9/21/07. Multiple other body parts and medical diagnoses have been added subsequently. The patient has continued to have multifocal pain and has undergone several surgical procedures and therapeutic injections. He has not worked since at least 9/15/09. His medical history is notable for alcohol abuse and obesity. On 5/13/14, the patient was evaluated by a physicians' assistant in a pain specialist's office. No complaints are documented. Exam findings include tenderness and decreased range of motion of the back and multiple other joints. The documented medications include Norco, gabapentin, Sentra PM, muscle relaxers, fluoxetine, Neurontin, "as well as the compounds". Diagnoses include lumbar sprain/strain, lumbar radiculopathy, chronic pain syndrome, cervical spine sprain/strain with disc protrusions, bilateral knee pain with internal derangement; status post left shoulder surgery, and right trochanteric bursitis. Plan includes continuing Norco for breakthrough pain, starting Theramine two tablets twice per day for pain, continuing gabapentin and Sentra PM and continuing two topical compounded creams. Theramine was non-certified in UR on 6/17/14.

### 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 dates of service 5/13/14: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain chapter, Medical Foods

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation The MTUS Guidelines do not address the use of medical foods in general, or of Theramine in particular. Official Disability Guidelines (ODG), Pain section, Medical Foods.

**Decision rationale:** Theramine is an FDA-regulated medical food, and consists of a proprietary blend of amino acids. According to the FDA definition, medical foods are for treatment of specific dietary conditions and deficiencies. The ODG reference cited above quotes the FDA and states that to be considered, the product must be labeled for dietary management of a specific medical disorder, disease or condition for which there are distinctive nutritional requirements. These conditions include such entities as liver deficiency, achlorhydria, epilepsy, and others. The clinical documentation in this case does not support the provision of Theramine to this patient. He does not have any documented condition with distinct nutritional requirements, and no documentation of any condition which requires supplementation with amino acids specifically. A medical food is not indicated for pain, which is the stated reason for prescribing Theramine. Based on the guidelines cited above, on the FDA requirements for medical food use, and on the clinical records available for my review, Theramine is not medically necessary. It is not medically necessary because it is a medical food, and the requirements for prescription of a medical food have not been met.