

<b>Case Number:</b>	CM13-0040018		
<b>Date Assigned:</b>	12/20/2013	<b>Date of Injury:</b>	12/26/2000
<b>Decision Date:</b>	01/30/2014	<b>UR Denial Date:</b>	10/02/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/08/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation 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 physician 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 claimant is a 45 year old female who has an injury to the lumbar spine with a date of injury of December 26, 2000. She's had a L4-SI fusion. She has ongoing low back pain and left lower extremity pain. She had recent epidural steroid injections. Medical record dated 10/11/2013 from [REDACTED] stated: "The patient suffers from ongoing severe chronic pain. I would opine that it is very appropriate and necessary for this patient to be approved for the use of Theramine, a medical food, in the management of this condition. This course of treatment has proven to be effective and has demonstrated to be palliative in the treatment of chronic pain."

### 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 ODG 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, Theramine, USFDA, and PAINWEEK2012-MPR

**Decision rationale:** CA-MTUS (Effective July 18, 2009) is MUTE on Theramine therapy. According to the USFDA website, The term medical food, as defined in section 5(b) of the

Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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 drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. For example, medical foods do not have to undergo premarket review or approval."

ODG Theramine Not recommended. Theramine® is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer's study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 20 12) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. According to a recent study published in MPR and online drug information resource, Theramine, a prescription-only amino acid food product, may offer a safe alternative to traditional pharmaceutical products used to treat chronic back pain, according to a presentation at PAINWeek 2012. Theramine is prescribed for patients with chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain who cannot use conventional diets or supplements. It had been shown in a previous double-blind clinical trial to be effective in the treatment of chronic low back pain when compared with naproxen, a nonsteroidal anti-inflammatory drug (NSAID). [REDACTED], from Targeted Medical Pharma, Inc., in Los Angeles, and colleagues reported the results of the randomized, double-blind, placebo-controlled that examined if medical foods can offer an alternative therapeutic approach for back pain, with fewer side effects. In 127 patients, the efficacy of Theramine for chronic back pain was compared with low-dose ibuprofen, an NSAID. Patients were randomized to one of three treatment arms: low-dose ibuprofen (n=42), Theramine (n=42), or a combination of Theramine and ibuprofen