

<b>Case Number:</b>	CM14-0159040		
<b>Date Assigned:</b>	10/02/2014	<b>Date of Injury:</b>	10/13/2000
<b>Decision Date:</b>	12/02/2014	<b>UR Denial Date:</b>	09/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/29/2014

### 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 Occupational Medicine and is licensed to practice in Illinois. 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 worker is a 54 years old woman with a date of injury on 10/13/2000. According to clinical notes of April 25, 2014, she has persistent stabbing 9/10 low back pain, aching 9/10 cervical pain, and stabbing 9-10/10 bilateral foot and ankle pain. She takes Percocet, Lyrica, Ambien and Nexium and undergoes physical therapy which she states is helping. She has had an L5-S1 fusion surgery. An exam is noted for tenderness in the base of the cervical spine and in the trapezius, significant restriction in the range of motion of the cervical spine, tenderness in the lumbar spine paraspinal area, and significant restriction in the range of motion of the lumbar spine, neck, low back and right knee.

### 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 cite any medical evidence for its decision.

**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®

**Decision rationale:** Theramine is a medical food from [REDACTED], 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. Theramine is not addressed for the treatment of chronic pain in the Medical Treatment Utilization Schedule (MTUS). Per the Official Disability Guidelines (ODG), theramine is not recommended for the treatment of chronic pain. In Medical food, gamma-aminobutyric acid (GABA), 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 study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Theramine significantly improves chronic low back pain and reduces inflammation compared with low-dose ibuprofen, according to this randomized controlled trial (RCT) funded by the manufacturer. Criticisms of the study include that it was performed by the company that makes that product and conducted at commercial sites funded by the same manufacturer, the paper doesn't include the raw data on outcomes, only percentages of improvement, and doesn't discuss issues such as the success of blinding and injured worker adherence. Plus there is little information on the study injured workers and how they were recruited. (Shell, 2014) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The request is not medically necessary.

**AppTrim #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physician Therapeutics <http://ptlcentral.com/medical-foods-products.php> Food and Drug Administration <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm054048.htm>

**Decision rationale:** AppTrim is a Food and Drug Administration (FDA)-approved medical food for the nutritional management of obesity, morbid obesity and metabolic syndrome. AppTrim-D capsules by oral administration. A specially formulated medical food that must be administered under the ongoing supervision of a medical professional, consisting of a proprietary formula of amino acids and polyphenol ingredients in specific proportions, for the dietary management of the metabolic processes associated with obesity, morbid obesity, and metabolic syndrome. According to the Food and Drug Administration (FDA), 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." AppTrim is not addressed for the treatment of chronic pain in the Medical Treatment Utilization Schedule (MTUS), American College of Occupational and Environmental

Medicine (ACOEM) guidelines or the Official Disability Guidelines (ODG). Therefore, the request is not medically necessary.