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| Case Number: | CM13-0047290 | | |
| Date Assigned: | 12/27/2013 | Date of Injury: | 03/05/2007 |
| Decision Date: | 03/20/2014 | UR Denial Date: | 10/24/2013 |
| Priority: | Standard | Application Received: | 11/05/2013 |

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 Preventive Medicine, has a subspecialty in Occupational and Environment Medicine and is licensed to practice in Iowa. 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:

This patient is a 46-year-old female employee with date of injury of 3/5/2007. A review of her progress note by a physician dated 12/24/2013 identifies ongoing treatment for right shoulder surgery, two ulnar surgeries, neck pain, complex regional pain syndrome of the right upper extremity and low back pain. Objective findings include right elbow decreased range of motion, decreased range of motion with positive impingement, and tenderness of the right lower back. Subjective complaints include 9/10 pain that radiates to the right upper extremity and lower extremity. Treatment plan at the time recommended Cymbalta, Norco, Omeprazole, Dolgic and Theramine. The utilization review determination was rendered on 10/25/13 recommending non-certification of Theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

The retrospective request for Theramine (DOS) 8/27/2013 to 8/28/2013: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic pain, Medical foods.

Decision rationale: The patient is receiving ongoing treatment for right shoulder surgery, two ulnar surgeries, neck pain, complex regional pain syndrome of the right upper extremity and low back pain. Theramine is considered a medical food. The MTUS is silent on Theramine. ODG states "Not recommended. 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. 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 study comparing Theramine to naproxen; Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." In addition ODG states that a medical food is "Definition: 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 orally 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." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision." The request for Theramine is not medically necessary as its use is not supported in the Chronic Pain Medical Treatment and Official Disability Guidelines.