

Case Number:	CM13-0024562		
Date Assigned:	11/20/2013	Date of Injury:	08/02/1999
Decision Date:	01/22/2014	UR Denial Date:	08/30/2013
Priority:	Standard	Application Received:	09/16/2013

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 patient is a 53 year old female who was employed by [REDACTED], and sustained a work-related injury on 8/2/99. According to the medical reports dated 9/7/12, "the patient complains of right shoulder and neck pain, which is stable. She complained of right arm nagging pain in back of upper arm. She complained of increased stiffness in her neck. She is using the TENS, heat, and doing stretches. Patient complains of spasms in her neck, shoulders, and upper back. [REDACTED] feels it is intestinal spasm. She was given Librax, Bentyl, and Align. Patient is doing better with the pain, but has GERD [gastroesophageal reflux disease]. Patient uses TENS at night. Patient feels like her pain and function is getting worse due to recent changes in medications due to denials. Patient's physical therapy is over. The Ultram is not working." Her diagnoses include complex regional pain syndrome in the right upper extremity, cervical radiculitis, fibromyalgia, temporomandibular joint syndrome, carpal tunnel, and left shoulder impingement. She was advised to continue on GABA-2-K; Norco 10/325, half a tab three times a day, #60; and Tizanidine for spasms.

IMR ISSUES, DECISIONS AND RATIONALES

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

Therapentin-90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter: Medical Foods.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines section on Anti-Epileptics Page(s): 17. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter: Medical Foods; the United States Food and Drug Administration (USFDA) website, section on Medical Foods; NutritionalPharmacology.com; and a study cited by Physician Therapeutics.

Decision rationale: Therapentin-90 is a compound drug consisting of Theramine (a medical food), and Gabapentin (an anti-epileptic drug (AED)). According to the MTUS, AEDs are recommended on a trial basis as a first-line therapy for painful polyneuropathy, with diabetic polyneuropathy being the most common example; however, the MTUS is mute on Theramine, which is designed to aid in the nutritional management of pain symptoms. According to the United States Food and Drug Administration (USFDA) website, the term 'medical food' is 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 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 requisitions, 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. This medical food is not recommended by the Official Disability Guidelines (ODG) for chronic pain management. According to NutritionalPharmacology.com, Theramine is said to stimulate production of serotonin, GABA, norepinephrine, nitric oxide, and acetylcholine, the neurotransmitters that are involved in pain disorders. If the timing and secretion of these neurotransmitters are effectively modulated, acute and chronic pain disorders are more effectively managed. Theramine provides L-arginine in low doses along with choline and L-glutamine to inhibit the NMDA and opioid receptors, as well as aiding in the nutritional management of serotonin, GABA, and acetylcholine production deficiencies in patients with pain syndromes. There is no high quality peer-reviewed literature that suggests GABA is indicated in the treatment of chronic pain. Also, the excerpt from the ODG's pain chapter states, "There is no known medical need for choline supplement." With respect to L-arginine, the ODG states, "This medication is not indicated in current references for pain or inflammation." In the study cited by Physician Therapeutics, the manufacturer of Therapentin-90, it stated that when comparing Theramine to Naprosyn, Theramine appeared to be effective in relieving back pain without causing any significant side effects (Shell 2012); however, until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Thus, the request for Therapentin-90 is not medically necessary.

Trepadone, #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter: Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter: Medical

Foods; and the United States Food and Drug Administration (USFDA) website, section on Medical Foods.

Decision rationale: Trepadone is a medical food from Targeted Medical Pharma, Inc. It is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine, and GABA. It is intended for use in the management of joint disorders associated with pain and inflammation. The MTUS is mute on Trepadone. The United States Food and Drug Administration (USFDA) website defines 'medical food' 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 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 requisitions, 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. There is no high quality peer-reviewed literature that suggests GABA is indicated in the treatment of chronic pain. Also, the excerpt from the ODG's pain chapter states, "There is no known medical need for choline supplement." With respect to L-arginine, the ODG states, "This medication is not indicated in current references for pain or inflammation," and it states that there is no indication for use of L-serine. Based on the above, this request is not medically necessary.