

Case Number:	CM15-0195858		
Date Assigned:	10/09/2015	Date of Injury:	09/14/2011
Decision Date:	11/23/2015	UR Denial Date:	09/04/2015
Priority:	Standard	Application Received:	10/05/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 52 year old female, who sustained an industrial injury on 9-14-2011. The medical records indicate that the injured worker is undergoing treatment for cervical spine sprain-strain, rule out C7-8 radiculopathy, right shoulder sprain, impingement and frozen shoulder, bilateral elbow pain with medial epicondylitis, bilateral wrist sprain-strain with right De Quervain's, bilateral hand pain, and lumbar spine sprain, rule out left L5 radiculopathy. According to the progress report dated 8-17-2015, the injured worker presented with complaints of pain in the neck (7-8 out of 10), right shoulder (5-8 out of 10), bilateral elbows (7 out of 10), bilateral wrists-fingers (5-8 out of 10), and low back (6-8 out of 10). The physical examination reveals decrease range of motion in the cervical spine, bilateral shoulders, bilateral elbows, bilateral wrists, and lumbar spine. The current medications are Vicodin, Naprosyn, Ambien, Ativan, Narcosoft, and Citrucel. Previous diagnostic studies include x-rays, electrodiagnostic testing, and MRI studies. Treatments to date include medication management. Work status is described as permanent and stationary. The original utilization review (9-4-2015) had non-certified a request for Theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine BID #90 with 3 Refills: 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 (Online Version), Theramine, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Theramine and medical food.

Decision rationale: ODG states that a medical food is "a food which is formulated to be consumed or administered internally 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". ODG comments on Theramine directly, "Not recommended. Theramine is a medical food from [REDACTED], 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 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." The ODG guidelines do not support the use of Theramine. As such the request for Theramine BID #90 with 3 refills is not medically necessary.