

Case Number:	CM15-0117835		
Date Assigned:	06/26/2015	Date of Injury:	05/13/2011
Decision Date:	07/31/2015	UR Denial Date:	05/20/2015
Priority:	Standard	Application Received:	06/18/2015

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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 46 year old female, who sustained an industrial injury on May 13, 2011. She reported falling and waking up on the floor on her right side, diagnosed with a concussion and contusions of the right shoulder, right elbow, right knee and right hip. The injured worker was diagnosed as having abdominal pain, acid reflux, constipation/diarrhea, bright red blood per rectum, sleep disorder, cervical and lumbar strain, disc disease, depression, status post right shoulder surgery, and history of multiple falls. Treatment to date has included abdominal ultrasound, transthoracic echocardiogram, x-rays, head CT scan, physical therapy, MRIs, electrodiagnostic studies of the bilateral upper/lower extremities, right shoulder decompression June 2014, cortisone injections to the neck and back, nocturnal polysomnogram, trigger point injections, upper GI, and medication. Currently, the injured worker complains of headaches, dizziness, neck, right upper extremity, and back pain, vision problems, nausea and vomiting, and sleeping difficulties. The Treating Physician's report dated May 14, 2015, noted the injured worker reported falling 10-12 times in the last three years, losing strength in her right leg. The injured worker's current medications were listed as Nexium, Gaviscon, Citrucel, Probiotics, Amitiza, Fiorinal, Meclizine, Bentyl, Mycelex troches, Theramine, Trepadone, and PrevPak. Physical examination was noted to show a soft abdomen with normoactive bowel sounds. The injured worker's laboratory evaluations and abdominal ultrasound were noted to be unremarkable. The treatment plan was noted to include included medications prescribed / dispensed including as Nexium, Gaviscon, Citrucel, Probiotics, Amitiza, Bentyl, Theramine, and Trepadone.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine cap #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Online Version - Theramine.

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

Decision rationale: The MTUS is silent regarding Theramine. The Official Disability Guidelines (ODG) notes that Theramine is not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food 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 requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. 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 injured worker was noted to have an unremarkable abdominal examination, laboratory evaluation, and abdominal ultrasound. The Medical-Legal report dated March 2, 2015, noted the injured worker obese on a non-industrial basis, worsened on an industrial basis, noting the injured worker's heavy narcotic regimen contributing to her lower gastrointestinal (GI) problems. An upper GI dated March 24, 2015, was noted to be within normal limits. The documentation provided failed to include documentation of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements for the injured worker. Therefore, based on the MTUS guidelines, the documentation did not support the medical necessity of the request for Theramine cap #60.