

Case Number:	CM15-0071475		
Date Assigned:	04/21/2015	Date of Injury:	12/04/2003
Decision Date:	05/22/2015	UR Denial Date:	03/30/2015
Priority:	Standard	Application Received:	04/15/2015

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: Pennsylvania

Certification(s)/Specialty: Internal 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 63 year old female who sustained an industrial injury on December 4, 2003. The injured worker was diagnosed as having gastroesophageal reflux disease (GERD) secondary to non-steroid anti-inflammatory drugs (NSAIDs), hypertension secondary to chronic pain and stress, diabetes mellitus secondary to chronic pain and stress, hyperlipidemia secondary to hypertension and diabetes, sleep disorder secondary to chronic pain and stress, cervical spine radiculitis, right shoulder pain following revision arthroscopic rotator cuff repair 2010, left shoulder pain status post arthroscopy 2007, multilevel cervical disc desiccation and bulging with borderline stenosis, bilateral carpal tunnel syndrome status post bilateral carpal tunnel release, insomnia, stress syndrome, and depression/anxiety. Treatment to date has included cervical epidural injection, physical therapy, bilateral carpal tunnel release, left shoulder arthroscopy, right shoulder rotator cuff repair, and medication. Evaluation has included pulmonary stress test and echocardiography. Currently, the injured worker reports improving acid reflux, abdominal pain, and complains of difficulty sleeping, with uncontrolled blood pressure and blood sugar, lower back pain, and bilateral lower extremity pain. The secondary treating physician's report dated March 10, 2015, noted the injured worker had no tenderness or pain in the right lower quadrant, with an abdominal ultrasound pending. The treatment plan included gastrointestinal (GI), hypertension, and diabetes profiles, and Vitamin B12 laboratory evaluations. The injured worker's medications were listed as Amlodipine, Prilosec, Lovaza, Metformin, and Victoza, aspirin (ASA), Theramine, Trepadone, Gabadone, and Sentra AM. The physician recommended a low-fat, low-acid, low-cholesterol, low-sodium, low-glycemic diet. On 3/30/15, Utilization

Review (UR) non-certified requests for Sentra AM #60, gabadone #60, Theramine #60, and Trepadone #90, citing the MTUS, the ODG, the US National Institutes of Health National Library of Medicine PubMed, and the Physician's Desk Reference.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM Quantity requested 60.00: 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), Chronic pain - medical food, US National Institutes of Health (NIH) National Library of Medicine (NLM) PubMed 2010 (<http://www.ncbi.nlm.nih.gov/pubmed/>).

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

Decision rationale: Sentra AM is a medical food intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory. 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. There is no documentation of a specific nutritional deficiency, which would be expected to be improved with this medical food. The ODG states that 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. As medical foods are not recommended by the guidelines, the request for Sentra AM is not medically necessary.

Gabadone Quantity requested 60.00: 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), Chronic pain - medical food, US National Institutes of Health (NIH) National Library of Medicine (NLM) PubMed 2010 (<http://www.ncbi.nlm.nih.gov/pubmed/>).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: Gabadone, insomnia treatment, medical food.

Decision rationale: Gabadone is a medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for

sleep disorders and sleep disorders associated with insomnia. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. The treating physician documented that the injured worker had difficulty sleeping, but no evaluation of the potential causes of sleep disturbance was documented. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Gabadone is not recommended for sleep disorders based on limited available research. As this agent is not recommended by the guidelines, the request for Gabadone is not medically necessary.

Theramine Quantity requested 60.00: 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), Chronic pain - medical food, US National Institutes of Health (NIH) National Library of Medicine (NLM) PubMed 2010 (<http://www.ncbi.nlm.nih.gov/pubmed/>).

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

Decision rationale: 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. There is no documentation of a specific nutritional deficiency, which would be expected to be improved with this medical food. The ODG states that 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. Theramine is medical food intended for use in the management of chronic pain syndromes which 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%). Per the ODG, theramine is not recommended for the treatment of chronic pain. As this agent is not recommended by the guidelines, the request for theramine is not medically necessary.

Trepadone Quantity requested 90.00: 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), Chronic pain - medical food.

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

Decision rationale: Treadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, and chondroitin. There is insufficient evidence to support use of this medical food for osteoarthritis or for neuropathic pain. The ODG states that Treadone is not recommended. 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. There is no documentation of a specific nutritional deficiency, which would be expected to be improved with this medical food. As this agent is not recommended by the guidelines, the request for Treadone is not medically necessary.