

Case Number:	CM15-0003171		
Date Assigned:	01/14/2015	Date of Injury:	11/12/2010
Decision Date:	03/24/2015	UR Denial Date:	12/16/2014
Priority:	Standard	Application Received:	01/07/2015

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: Indiana

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 64 year old male, who sustained an industrial injury on 11/12/2010. The current diagnoses are sleep disorder secondary to pain; rule out obstructive sleep apnea, constipation, and gastroesophageal reflux disease. Currently, the injured worker complains of mild bloating. Additionally, he reports poor sleep quality, sleeping only 4-5 hours per night secondary to pain and stress. He does report improving abdominal pain and reflux with medications. Current medications are Dexilant, Colace, and Sentradine. The treating physician is requesting Trepadone #60 x 3 bottles and Theramine #60 x 3 bottles, which is now under review. On 12/16/2014, Utilization Review had non-certified a request for Trepadone #60 x 3 bottles and Theramine #60 x 3 bottles. The Official Disability Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trepadone #60 x 3 bottles: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain; Trepadone

Decision rationale: MTUS is silent on this issue, but ODG states the following: "Not recommended for the treatment of chronic pain. Trepadone is a medical food from [REDACTED], that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gamma aminobutyric acid (GABA). It is intended for use in the management of joint disorders associated with pain and inflammation. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA)." Therefore, the request for Trepadone is not medically necessary.

Theramine #60 x 3 bottles: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain; Theramine

Decision rationale: MTUS is silent on this issue, but ODG states the following: "Not recommended for the treatment of chronic pain. 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) Theramine significantly improves chronic low back pain and reduces inflammation compared with low-dose ibuprofen, according to this RCT funded by the manufacturer. Criticisms of the study include that it was performed by the company that makes that product and conducted at commercial sites funded by the same manufacturer, the paper doesn't include the raw data on outcomes, only percentages of improvement, and doesn't discuss issues such as the success of blinding and patient adherence. Plus there is little information on the study patients and how they were recruited. (Shell, 2014) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." Therefore, the request for Theramine is not medically necessary.