

Case Number:	CM14-0058902		
Date Assigned:	07/09/2014	Date of Injury:	06/16/2002
Decision Date:	09/09/2014	UR Denial Date:	04/15/2014
Priority:	Standard	Application Received:	04/29/2014

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. The expert reviewer is Board Certified in Anesthesiology has a subspecialty in Pain Management 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 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/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:

This is a 54-year-old female with a 6/13/02 date of injury. The mechanism of injury was not provided. According to a progress report dated 3/31/14, the patient complained of pain in both arms, both shoulders, and the neck. She also complained of not having enough sleep. Objective findings: limited to vital signs. Diagnostic impression: cervical radiculopathy status post cervical fusion, neck pain, chronic pain syndrome, chronic pain-related insomnia, myofascial syndrome, neuropathic pain. Treatment to date: medication management, activity modification. A UR decision dated 4/15/14 denied the requests for Theramine and Trepadone. The rationale for denial was not provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #60: 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 Official Disability Guidelines (ODG) Pain ChapterX Other Medical Treatment Guideline or Medical Evidence:
<http://nutrientpharmacology.com/PDFs/monographs/trepadone-monograph.pdf>.

Decision rationale: CA MTUS does not address this issue. ODG states that Theramine is not recommended. There is no high quality peer-reviewed literature that suggests that GABA is indicated. There is no known medical need for choline supplementation; L-Arginine is not indicated in current references for pain or inflammation; L-Serine is not indicated. In a manufacturer study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. It is documented that the provider has prescribed Theramine for the patient's neuropathic pain. However, a specific rationale identifying why Theramine would be required in this patient despite lack of guideline support was not provided. Therefore, the request for Theramine #60 is not medically necessary

Trepadone #120: 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 Official Disability Guidelines (ODG) Pain Chapter.

Decision rationale: CA MTUS does not address this issue. According to an online search, Trepadone is intended for use in the management of joint disorders associated with pain and inflammation. Trepadone is a medical food that must be used in patients who are under the active and ongoing supervision of a physician. Trepadone is a proprietary blend of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine) and neurotransmitters (gamma-amino butyric acid [GABA]); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory compounds (omega-3 fatty acids and histidine); immunomodulatory peptides (whey protein hydrolysate); precursors of functional components of joint connective tissue (glucosamine and chondroitin sulfate); and an adenosine antagonist (cocoa powder). However, the FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. It is documented that the provider has prescribed Trepadone for the patient's joint health. Guidelines do not support the use of medical foods unless it is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. There is no documentation that the patient is deficient of any of the ingredients contained in Trepadone. A specific rationale identifying why Trepadone would be required in this patient despite lack of guideline support was not provided. Therefore, the request for Trepadone #120 is not medically necessary.