

Case Number:	CM14-0036188		
Date Assigned:	03/26/2014	Date of Injury:	08/24/2005
Decision Date:	10/07/2014	UR Denial Date:	02/06/2014
Priority:	Standard	Application Received:	02/20/2014

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 Physical Medicine & Rehabilitation and is licensed to practice in Georgia. 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:

The patient is a 60 year old female who was injured on 08/28/2005. The mechanism of injury is unknown. The patient underwent epidural steroid injection which provided temporary relief of symptoms. Prior medication history included Vicodin 7.5 mg, Motrin 800 mg, and Theramine #60. Ortho note dated 09/11/2013 documented the patient to have complaints of neck pain rated as 7/10 with associated numbness and weakness in bilateral hands, and low back pain rated as 6/10. Objective findings on exam revealed 4+ palpable hypertonicity noted bilaterally. Cervical spine range of motion produced pain and spasm. Cervical flexion to 40 degrees; extension to 20 degrees; right rotation to 45; left rotation 50; lateral flexion on the right at 30; and left lateral flexion at 30. The patient is diagnosed with cervical disc syndrome; cervical spondylosis, herniated disc, and lumbar sprain/strain. The patient is recommended for Theramine #120 to assist in decreasing the patient's pain and symptoms. Prior utilization review dated 02/06/2014 states the request for Theramine is not certified based on evidence submitted.

IMR ISSUES, DECISIONS AND RATIONALES

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

THERAMINE: 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, Theramine & Medical food Other Medical Treatment Guideline or Medical Evidence:
<http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>

Decision rationale: The above ODG guidelines on Theramine states "Not recommended. Theramine is a medical food from [REDACTED] that is a proprietary blend of gamma-amino butyric 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-amino butyric 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." In this case, there are no documented indications to recommend Theramine. Therefore, based on the above guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.