MAXIMUS Federal Services

Case Number:	CM14-0000537		
Date Assigned:	01/10/2014	Date of Injury:	08/20/2003
Decision Date:	06/23/2014	UR Denial Date:	12/04/2013
Priority:	Standard	Application Received:	01/02/2014

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 Occupational Medicine 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 50-year-old female patient with an 8/20/2003 date of injury. 12/12/2012 progress report indicates stiffness and tightness of the C-spine and right shoulder. He also noted numbness and tingling in the upper extremities when sleeping or driving. The patient was on Theramine, Lyrica and Mobic. She noted shoulder pain improved to 4/10 from 8/10. On physical exam, cervical extension was 30 degrees, right lateral bend was 30 degrees, left lateral bend was 25 degrees. There was mild AC joint tenderness, mild pain and weakness on manual resistive muscle strength testing. Doctor reported patient's condition improvement with trigger point injections and initiation of oral medication. From 02/01/2013 to 04/12/2013, the patient's condition hadn't changed, as well as her medication. On 04/12/2013, her clinical diagnosis was thoracic outlet syndrome. The patient had failed conservative therapy including exercises, ergonomic adjustments, physical therapy, analgesics and anti-inflammatory drugs. A test block of the scalene and pectoralis minor was being performed to determine if the patient could be confirmed to have thoracic outlet syndrome and whether the patient was a candidate for surgical decompression. From 04/26/2013 to 07/03/2013, there are unchanged complaints of muscle spasm and stiffness. There is documentation of a previous determination on 12/4/2013, according to ODG, until there are higher quality studies of the ingredients in Theramine, it remains not recommended.

IMR ISSUES, DECISIONS AND RATIONALES

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

PHARMACY-THERAMIN #90: 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) Pain chapter, Theramine.

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, Theramin

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. The patient presented with muscle spasm, stiffness and tightness of C spine. She was prescribed Theramine, Lyrica and Mobic. From 02/01/2012 to 07/03/2013, her complaints were changing from sharp pain to less pain. She never reported being without pain. However, there remains adverse guidelines evidence for Theramine. There is no high-quality peer-reviewed literature to support Theramine treatment. The requesting provider did not indicate special circumstances that would necessitate Theramine treatment despite evidence. In addition there was no documented evidence of the patient's response to previous Theramine treatment. Therefore, the request for Pharmacy-Theramine #90 is not medically necessary.