

Case Number:	CM14-0003770		
Date Assigned:	01/29/2014	Date of Injury:	06/29/2005
Decision Date:	12/30/2014	UR Denial Date:	01/07/2014
Priority:	Standard	Application Received:	01/07/2014

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 56-year-old female with a 6/29/05 date of injury. According to a progress report dated 11/13/13, the patient indicated that she has had increasing neck and low back pain. Objective findings: tenderness to palpation of cervical spine, limited cervical range of motion, sensation decreased along the median nerve in the bilateral upper extremities, paravertebral tenderness of lumbosacral spine, and limited lumbosacral spine range of motion. Diagnostic impression: right carpal tunnel syndrome, right shoulder impingement syndrome, chronic lumbar spine sprain/strain. Treatment to date includes medication management, activity modification, and physical therapy. A UR decision dated 1/7/14 denied the requests for Prazolamine and Theratramadol, dispensed 11/13/13. Theramine is a medical food product advertised to aid in the nutritional management of pain syndromes. There is no objective evidence that compounding the amino acid with Carisoprodol or Tramadol is any more effective than the generic medications without Theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective: Prazolamine (Theramine and Carisoprodol) 250mg #60 (DOS: 11-13-2013): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol Page(s): 29, 65. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter - Theramine; Other Medical Treatment Guideline or Medical Evidence: FDA (Carisoprodol)

Decision rationale: The California MTUS does not address the issue of Theramine. Official Disability Guidelines 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. However, in the present case, this is a request for a compounded medication containing Theramine and Carisoprodol. A specific rationale identifying why Theramine would be required in this patient despite lack of guideline support was not provided. In addition, it is unclear how long this patient has been taking Carisoprodol, and guidelines do not support its long-term use. There is no documentation of subjective complaints or objective findings indicating spasms in this patient. There is no documentation that this patient has had an exacerbation of her pain. Furthermore, guidelines do not support the use of compounded medications when the ingredients are available separately. However, the medical necessity of the separate ingredients of this medication has not been established. Therefore, the request for Retrospective: Prazolamine (Theramine and Carisoprodol) 250mg #60 is not medically necessary.

Retrospective: Theratramadol-60 (Theramine and Tramadol) 50mg #120 (DOS: 11-13-2013): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opiates; Tramadol Page(s): 29, 65; 78-81; 113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter - Theramine

Decision rationale: The California MTUS does not address the issue of Theramine. Official Disability Guidelines 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. However, in the present case, this is a request for a compounded medication containing Theramine and Tramadol. A specific rationale identifying why Theramine would be required in this patient despite lack of guideline support was not provided. In addition, it is unclear how long this patient has been taking Tramadol. There is no documentation of significant pain reduction or improved activities of daily living from previous opioid use. There

is no documentation of lack of aberrant behavior or adverse side effects, an opioid pain contract, urine drug screen, or CURES monitoring. Furthermore, guidelines do not support the use of compounded medications when the ingredients are available separately. However, the medical necessity of the separate ingredients of this medication has not been established. Therefore, the request for Retrospective: Theratramadol-60 (Theramine and Tramadol) 50mg #120 is not medically necessary.