

Case Number:	CM13-0059256		
Date Assigned:	04/25/2014	Date of Injury:	05/30/1995
Decision Date:	06/12/2014	UR Denial Date:	11/21/2013
Priority:	Standard	Application Received:	12/01/2013

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 Emergency Medicine, and is licensed to practice in New York. 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 63-year-old male who was injured on May 30, 1995. The patient continued to experience low back pain and sciatica. The physical examination was notable for tenderness and spasm in the lumbar paraspinal muscles, positive straight leg raise bilaterally, decreased sensation on the left and right L5-S1 distribution, and mild left lower extremity weakness. The diagnoses included sciatica and lumbago. The treatment included aqua therapy, medication, and epidural steroid injections. The requests for authorization for theramine and soma 350 mg were submitted for consideration.

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 base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG); ODG-TWC; ODG TREATMENT; INTEGRATED TREATMENT/DISABILITY DURATION GUIDELINES, PAIN CHAPTER, MEDICAL FOODS.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, MEDICAL FOODS, THERAMINE.

Decision rationale: Theramine is a medical food 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. Medical Food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. GABA is indicated for epilepsy, spasticity and tardive dyskinesia. There is no documentation that any of these conditions is present in the patient. Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. The side effects of high-dose choline include hypotension, acute gastrointestinal (GI) distress, and cholinergic side effects (such as sweating and diarrhea). There is no indication for the use of serine. Arginine is not indicated in current references for pain or inflammation. Theramine is not recommended under the Official Disability guidelines. The request should not be authorized.

SOMA 350MG: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 7/18/2009, CARISOPRODOL (SOMA), Page(s): 29.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CARISOPRODOL (SOMA), Page(s): 29.

Decision rationale: Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Abuse has been noted for sedative and relaxant effects. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. These drugs include cocaine, tramadol, hydrocodone, benzodiazepines, and alcohol. A withdrawal syndrome has been documented that consists of insomnia, vomiting, tremors, muscle twitching, anxiety, and ataxia when abrupt discontinuation of large doses occurs. Carisoprodol is not recommended. The request should not be authorized.