

Case Number:	CM14-0034393		
Date Assigned:	06/20/2014	Date of Injury:	05/21/2007
Decision Date:	07/18/2014	UR Denial Date:	03/05/2014
Priority:	Standard	Application Received:	03/19/2014

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 and Rehabilitation, has a subspecialty in Sports Medicine and is licensed to practice in Texas and 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 injured worker who is a 56- year- old male who reported an injury on 05/21/2007 due to an unknown mechanism. On 02/21/2014 the injured worker complained of low back pain. He states that Subutex helps with the pain more than Troches which was less effective. The injured worker states that he has been attending physical therapy and it has helped a great deal with pain and has improved his function. The injured worker states that his pain level with medication was 5/10 and without 9/10. The objective findings lacked range of motion. It was noted that the injured worker will do a urine drug screen as recommended by ACEOM. The injured worker medication includes Fioricet 50/325mg, Subutex 8mg, Tramadol 50mg, Celebrex 200mg, Anaprox 550mg, Prilosec 20mg, Elavil 25mg, Colace 100mg, Viagra 50mg and Theramine. The injured worker diagnoses include lumbar radiculopathy status post lumbar fusion, chronic pain syndrome, traumatic arthropathy, status post left thumb carpometacarpal joint with complete trapeziectomy, radiculopathy, chronic pain related insomnia, prescription narcotic dependence, myofascial syndrome, chronic pain related anxiety, neuropathic pain, bilateral wrist sprain/strain and chronic pain related depression. The treatment plan included for a decision for Theramine 2 po BID #120/denied by Physician Advisor Peer Reviewer. The authorization for request was not submitted for this review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine 2 po BID #120/denied by Physician Advisor Peer Reviewer: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Theramine.

Decision rationale: The Official Disability Guidelines (ODG) does not recommend Theramine. 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. "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. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety. Dose reductions are indicated for a creatinine clearance > 60 ml/min. In this low quality RCT, with no description for the actual sleep disorder, an amino acid preparation containing both GABA and 5-hydroxytryptophan reduced time to fall asleep, decreased sleep latency, increased the duration of sleep, and improved quality of sleep L-Serine. There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement. The injured worker diagnoses include lumbar radiculopathy status post lumbar fusion, chronic pain syndrome, traumatic arthropathy, status post left thumb carpometacarpal joint with complete trapezectomy, radiculopathy, chronic pain related insomnia, prescription narcotic dependence, myofascial syndrome, chronic pain related anxiety, neuropathic pain, bilateral wrist sprain/strain and chronic pain related depression. The documents that were submitted for review lacked evidence contraindications of the medications that are prescribed to the injured worker and medication management. In addition, it was stated that the injured worker will do a urine test for medication compliance however, there was not one submitted for this review. Given the above, the request for Theramine 2 po BID #120 is not medically necessary.