

Case Number:	CM14-0176840		
Date Assigned:	10/30/2014	Date of Injury:	02/03/2003
Decision Date:	12/18/2014	UR Denial Date:	09/26/2014
Priority:	Standard	Application Received:	10/24/2014

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 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 65-year-old female who was injured on July 21, 2013. The patient continued to experience pain in her lower back. Physical examination was notable for antalgic gait, tenderness in the left lumbar paravertebral regions in the L4-5 and L5-S1 levels, tenderness in the left sacroiliac joint, and restricted range of motion of the lumbar spine. Diagnoses included lumbosacral neuritis/radiculitis, lumbar sprain/strain, facetal syndrome, and myalgia/myositis. Treatment included medications and home exercise program. Request for authorization for Therabenzaprine #90 was submitted for consideration

IMR ISSUES, DECISIONS AND RATIONALES

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

Therabenzaprine #90 convenience pack (Theramine #90/Cyclobenzaprine 10mg #60):
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions Page(s): 63. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine, Medical Food

Decision rationale: This is a medication containing Theramine, a medical food, and Cyclobenzaprine, a muscle relaxant. Theramine is a medical food from [REDACTED], [REDACTED], 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 internally 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. Side effects of high-dose choline include hypotension, acute 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 ODG. Cyclobenzaprine is recommended as an option, for a short course of therapy. It has been found to be more effective than placebo with greater adverse side effects. Its greatest effect is in the first 4 days. Treatment should be brief. Non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment (less than two weeks) of acute exacerbations in patients with chronic low back pain (LBP). Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. The duration of treatment surpasses the recommended short-term duration of two weeks. The medication is not recommended. The convenience pack contains two medications that neither is recommended. The request is not medically necessary and appropriate.