

Case Number:	CM14-0111972		
Date Assigned:	09/16/2014	Date of Injury:	07/21/2000
Decision Date:	10/27/2014	UR Denial Date:	07/17/2014
Priority:	Standard	Application Received:	07/18/2014

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 & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Texas and Oklahoma. 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 is a 68-year-old male who reported an injury on 07/21/2000 due to an assault while working as a prison guard. The injured worker complained of lower back pain. The diagnoses included failed back syndrome with chronic pain, degeneration of the lumbosacral intervertebral disc, therapeutic drug monitoring, and long term use of meds and gait dysfunction. Diagnostics included an electromyogram which revealed chronic left radiculopathies at the L5 and S1. The past treatments included medications. The physical examination dated 08/29/2014 of the lumbar spine revealed bilateral tenderness at the L3-5 to the paraspinous muscles, decreased range of motion with extension at 20 degrees and flexion at 60 degrees, bilateral bending at 20 degrees and rotation at 70 degrees. Bilateral lower extremities revealed edema and redness. Neurological: decreased sensory to pinprick along bilateral lateral leg and toes, weakness to the bilateral legs. The spine revealed hunched over with assistance of a cane. Treatment plan included current medication regimen. The medications included morphine sulfate, Voltaren, Flexeril, Prilosec and Norco. The Request for Authorization form dated 09/16/2014 was submitted with documentation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sprix #5: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Sprix nasay spray

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

Decision rationale: The request for Sprix #5 is not medically necessary. The Official Disability Guidelines indicate that Sprix was approved by the FDA in intranasal formulation of ketorolac tromethamine (nasal spray) for short term management of moderate to moderately severe pain requiring an analgesic to the opioid level. The total duration of the use of the intranasal formulation as with other ketorolac formulations should be for the shortest duration possible and not exceed 5 days. Both studies used for approval were for short term pain after abdominal surgery, so it is not recommended as a first line medication for chronic pain. The clinical note did not indicate that the injured worker had had any abdominal surgery. The guidelines indicate that Sprix is used for short term duration of 5 days after abdominal surgery. The request did not indicate the frequency or the dosage. As such, the request is not medically necessary.

Theramine #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, 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

Decision rationale: The request for Theramine #90 is not medically necessary. Theramine is comprised of Choline Bitartrate, L-Arginine, L-Histidine, L-Glutamine, L-Serine, GABA, Griffonia Seed (20% 5HTP), Whey Protein, Grape Seed Extract, Ginkgo Biloba, Cinnamon, and Cocoa. The Official Disability Guidelines note Theramine is not recommended. 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. 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. There is no indication for the use of L-Serine. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. There is no indication that the injured worker has been on long-term parenteral nutrition or has a choline deficiency secondary to liver deficiency. Additionally, the guidelines do not recommend the use of Theramine as there is a need for higher quality studies of the ingredients in Theramine. The request did not indicate the frequency or the dosage. As such, the request is not medically necessary.

Sentra AM #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, 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

Decision rationale: The request for Sentra AM #60 is not medically necessary. Sentra AM contains choline and acetylcarnitine. The Official Disability Guidelines medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "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." The guidelines note 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. Within the documentation it was not evident that the injured worker has been on long-term parenteral nutrition or has a choline deficiency secondary to liver deficiency. The request did not indicate the frequency or dosage. As such, the request is not medically necessary.

Sentra PM #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, 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

Decision rationale: The request for Sentra PM #60 is not medically necessary. Sentra PM is a medical food intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. 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 and there is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria; treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses and it is generally used for digestive disorders in complementary medicine. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders as well as for depression. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI antidepressants and it has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. There is no indication that the injured worker has sleep issues which would benefit from the

medication. There is no indication that the injured worker has been on long-term parenteral nutrition or has a choline deficiency secondary to liver deficiency. There is no evidence that the injured worker has impaired intestinal permeability, short bowel syndrome, cancer or a critical illness. The request did not indicate a frequency or dosage. As such, the request is not medically necessary.