

Case Number:	CM14-0114722		
Date Assigned:	09/23/2014	Date of Injury:	11/08/2013
Decision Date:	11/04/2014	UR Denial Date:	06/18/2014
Priority:	Standard	Application Received:	07/21/2014

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 Anesthesiology, has a subspecialty in Pain Medicine, and is licensed to practice in Florida. 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 55-year-old female who reported an injury on 11/08/2013, while working at the bakery, she developed lower back, right hand, wrist, right shoulder, and left knee pain, resulting from continuous use of the hands, wrists, and repetitive bending and lifting. The injured worker complained of neck, shoulder, hand, knee, and lower back pain. The diagnosis included lumbar disc syndrome with radiculopathy, knee sprain/strain, and wrist sprain/strain. The diagnostics included MRI to the lumbar spine dated 03/26/2004 that revealed spondylosis at the L4 and L5, disc desiccation noted to the L2-S1, disc bulge at the L2-3, neural foraminal narrowing at the L3-4, and neural foraminal narrowing at the L4-5 and L5-S1. Prior treatments included physical therapy, acupuncture, chiropractic therapy, medication, and ice. The objective findings to the lumbar spine revealed flexion 80 degrees, extension 20 degrees, tenderness and muscle guarding and splinting noted to the lumbar paraspinals, biceps femoris, and gluteal muscles. The Ely's and iliac compression test were positive bilaterally. Deep tendon reflexes 2+ bilaterally. Straight leg raise positive at 70 degrees bilaterally. The upper extremities revealed a flexion of 50 degrees bilaterally, extension 50 degrees bilaterally, with tenderness upon palpation of the ulnar eminence and carpal bones. The Finkelstein's and Flynn's test were positive on the right. The lower extremities revealed flexion 150 degrees bilaterally and extension 0 degrees bilaterally. Medications included Sentra AM, Sentra PM, Theramine, Narcosoft, and Terocin. The treatment plan included medications. The Request for Authorization was not submitted with documentation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Narcosoft, 2 capsules twice daily #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-Treatment Index, 12th Edition (web) 2014, Pain Chapter, Medical food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Medical Foods.

Decision rationale: The request for Narcosoft, 2 capsules twice daily #60, is not medically necessary. The California MTUS guidelines note during the initiation of opioid therapy, prophylactic treatment of constipation should be initiated. There is no indication that the injured worker is taking medications which cause constipation. There is no indication that the injured worker has complaints of constipation. The requesting physician's rationale for the request is not indicated within the provided documentation. As such, the request is not medically necessary.

Sentra AM, 2 capsules twice daily #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-Treatment Index, 12th Edition (web) 2014, Pain Chapter, Medical food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Medical Foods

Decision rationale: The request for Sentra AM 2 capsules twice daily #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 address the dosage. As such, the request is not medically necessary.

Sentra PM, 2 capsules twice daily #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-Treatment Index, 12th Edition (web) 2014, Pain Chapter, Medical food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain (chronic), Sentra PM & Medical food

Decision rationale: The request for Sentra PM 2 capsules twice daily #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 address the dosage. As such, the request is not medically necessary.

Theramine, two capsules every 4 hrs #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-Treatment Index, 12th Edition (web) 2014, Pain Chapter, Medical food

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

Decision rationale: The request for Theramine 2 capsules every 4 hours #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 address the dosage. As such, the request is not medically necessary.

Terocin, apply to affected area as needed #120ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic Page(s): 111-113.

Decision rationale: The request for Terocin, apply to affected area as needed, #120 mL is not medically necessary. Terocin cream is comprised of methyl salicylate, capsaicin, menthol, and lidocaine. The California MTUS Guidelines state that topical compounds are largely experimental in use with few randomized control trials to determine efficacy or safety; and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Additionally, any compounded product that contains at least 1 drug that is not recommended is not recommended. The guidelines state that capsaicin is recommended only as an option in injured workers who have not responded to or are intolerant to other medications. The guidelines do not recommend topical lidocaine in any other forms other than Lidoderm. The documentation included did not indicate that the injured worker had not responded to or not tolerated any other treatments. The medical documentation lacked evidence of a failed trial of antidepressants or anticonvulsants. The request did not indicate the dosage. As such, the request is not medically necessary.