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| Case Number: | CM13-0047660 | | |
| Date Assigned: | 12/27/2013 | Date of Injury: | 04/17/2012 |
| Decision Date: | 07/30/2014 | UR Denial Date: | 10/17/2013 |
| Priority: | Standard | Application Received: | 11/04/2013 |

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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in California. 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:

This is a 59-year-old female with a 4/17/12 date of injury. Mechanism of injury is described in the records however does not make sense. Described as lifting a "dead body". The notes describe chronic bilateral low back pain with radiation down the left lower extremity below the knee into the ankle. Physical exam revealed positive straight leg raise on the left and a positive Lasegue's test on the left; flexion was 40 degrees with mild to moderate pain, extension was 0 degrees, right and left lateral flexion caused low back pain with radiation to the leg; facet joint provocation on the right side caused pain radiated to the left leg; facet provocation/neural foraminal provocation on the left side caused the same. There was moderate tenderness over the lumbar facets and moderate muscle spasm. Reflexes were +2 on bilateral knees and trace on bilateral ankles. VAS score 7-8/10, significantly interfering with sleep. The pain is aggravated by extension and flexion. The claimant uses a cane to ambulate. The diagnoses include lumbar radiculopathy. Medications listed include Flexeril, Gabapentin, Norco, Omeprazole, Naproxen, Sentra and Theramine. The treating provider requested Sentra take 2 daily at bedtime for sleep #60 and Theramine tid for pain and inflammation #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE PRESCRIPTION OF SENTRA, TAKE 2 DAILY AT BEDTIME FOR SLEEP, #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 (ODG) Pain, Sentra PM.

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

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. According to ODG, Sentra PM is intended for use in management of sleep disorders associated with depression. Sentra PM 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. Glutamic Acid is used for treatment of hypochlorhydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. A 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, the patient's sleep difficulty is reported to be due to the persistent low back pain, and not due to a circadian rhythm disorder. There is also no documentation regarding nutritional deficiencies in this patient. Also, the present request as submitted failed to specify the date of service for review. Therefore, the request for retrospective prescription of sentra, take 2 daily at bedtime for sleep, #60 is not medically necessary.

RETROSPECTIVE PRESCRIPTION OF THERAMINE, TAKE 1 TID FOR CHRONIC PAIN AND INFLAMMATION, #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 (ODG) Pain, Theramine.

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

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. According to ODG, Theramine is not recommended. It is a medical food that is a proprietary blend of GABA and choline bitartrate, L-arginine, and L-serine intended for management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Regarding GABA, there is no high quality peer-reviewed literature that suggests that GABA is indicated. Regarding choline, there is no known medical need for supplementation. Regarding L-Arginine, this medication is not indicated in current references for pain or inflammation. Regarding L-Serine, there is no indication for the use of this product. In this case, patient was prescribed Theramine since 09/18/2012. However, guidelines do not support the use of Theramine. Also, the medical records

do not provide a compelling indication for variance from the guidelines. Finally, the present request as submitted failed to specify the date of service in for review. Therefore, the request for retrospective prescription of Theramine, take 1 three times a day for chronic pain and inflammation, #90 is not medically necessary.