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| Case Number: | CM14-0063703 | | |
| Date Assigned: | 07/11/2014 | Date of Injury: | 10/04/2007 |
| Decision Date: | 09/08/2014 | UR Denial Date: | 04/21/2014 |
| Priority: | Standard | Application Received: | 05/06/2014 |

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 Geriatrics and Internal 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:

The injured worker is a man with a date of injury of 10/4/7. He was seen by his physician on 8/5/14 and there is only one clinical note included in the records. The injured worker stated that he was unable to obtain his pain medications and that with medications he could do his activities of daily living (ADLs). He complained of pain radiating down both legs. His medical history included obesity, asthma, diabetes, hypertension, hypercholesterolemia and sleep apnea (uses CPAP). His physical exam showed unlabored breathing and he was in no distress. He used a motorized wheelchair for ambulation and could walk short distances unassisted. He had tenderness with spasms over the L3-S1 paraspinal muscles. The motor exam was normal to the upper and lower extremities and he had decreased range of motion in his lumbar spine. He was described as awake, alert and oriented with no focal neurological deficits. He had chronic pain syndrome, lumbago, obesity and muscle spasm. His medications included Opana, Flexeril, Ketoprofen Cream, Anaprox and Prilosec. The issue in this review is Theramine prescribed to help absorption of his NSAID, Sentra PM to help with sleep and Sentra AM to help with alertness and energy.

IMR ISSUES, DECISIONS AND RATIONALES

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

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 Pain (updated 4/10/14) Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Sentra PM: Treatment of Insomnia and http://nutrientpharmacology.com/sentra_AM.html and <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>.

Decision rationale: Sentra PM is a medication food. Patients with insomnia should receive therapy for any medical condition, psychiatric illness, substance abuse, or sleep disorder that may cause or worsen the problem and receive advice regarding sleep hygiene. After this, cognitive behavioral therapy would be trialed first prior to medications. In this injured worker, his sleep pattern, hygiene or level of insomnia is not addressed though he does have a history of sleep apnea and is using CPAP. Additionally, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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 records do not substantiate why a medical food is being used instead of or in addition to traditional medications or other non-pharmacological means to address sleep issues. The request is not supported by the documentation and therefore, Sentra PM #60 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 Pain (updated 04/10/2014) Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Theramine FDA website: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/> is medical food used to treat chronic pain syndromes and low back pain.

Decision rationale: The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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 records do not substantiate why a medical food is being used instead of or in addition to traditional medications, especially to assist with NSAID absorption. Therefore the request for Theramine 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 Pain (updated 04/10/2014) Medical food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Sentra AM http://nutrientpharmacology.com/sentra_AM.html and <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>.

Decision rationale: Sentra AM is a medical food designed to increase and maintain the production of acetylcholine by peripheral neurons and brain cells. This injured worker has no history documented of cognitive dysfunction. Additionally, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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 records do not substantiate why a medical food is being used instead of or in addition to traditional medications. Therefore, the request for Sentra AM #60 is not medically necessary.