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| Case Number: | CM14-0197285 | | |
| Date Assigned: | 12/05/2014 | Date of Injury: | 01/12/2013 |
| Decision Date: | 01/15/2015 | UR Denial Date: | 10/22/2014 |
| Priority: | Standard | Application Received: | 11/24/2014 |

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 Family Practice and is licensed to practice in Ohio. 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 32-year-old male with a date of injury of January 12, 2013. He was crushed by a dumpster while at work. He complains of neck pain, upper back pain, and lower back pain radiating to the left lower extremity associated with weakness. An MRI scan of the lumbar spine revealed a 2 mm disc bulge at L5-S1 with no focal disc protrusion or significant canal/neuroforaminal stenosis. He has had 24 sessions of physical therapy/chiropractic. He had a lumbar epidural steroid injection September 11, 2014. The diagnoses include cervical sprain/strain, thoracic sprain/strain, left shoulder impingement, right knee internal derangement with a PCL tear, idiopathic autonomic neuropathy, and lumbar radiculitis. The physical exam reveals moderate to severe tenderness of the lumbar paraspinal muscles, a positive straight leg raise sign on the left, and an otherwise normal lower extremity neurologic examination. On November 7, 2014 he was prescribed Terocin patches, Methoderm gel, Norco 10/325 mg. and Somnicin capsules. At issue is a request for Somnicin capsules #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Somnicin Cap #30: 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: 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 (Chronic), Medical food, Insomnia Treatment, and Melatonin

Decision rationale: 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. 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Somnicin is a proprietary formulation containing vitamin B6, magnesium, tryptophan, and melatonin. Tryptophan is a supplement which has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective 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. In published studies melatonin shows potent analgesic effects in a dose-dependent manner, and melatonin has been shown to have analgesic benefits in patients with chronic pain. Also, the repeated administration of melatonin improves sleep and thereby may reduce anxiety, which leads to lower levels of pain. In this instance, there is no clear rationale for the use of Somnicin. The injured worker does not appear to have a sleep disorder, a magnesium deficiency, or a vitamin B6 deficiency. Consequently, Somnicin Cap #30 is not medically necessary.