MAXIMUS Federal Services

Case Number:	CM15-0045398		
Date Assigned:	03/17/2015	Date of Injury:	08/12/2011
Decision Date:	04/23/2015	UR Denial Date:	02/12/2015
Priority:	Standard	Application Received:	03/10/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Ohio, North Carolina, Virginia
Certification(s)/Specialty: Family Practice

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 59-year-old female, who sustained an industrial injury on 8/12/2011. The current diagnoses are cervical spine herniated nucleus pulposus, lumbar spine herniated nucleus pulposus, and left shoulder rotator cuff tear. According to the progress report dated 2/7/2015, the injured worker complains of insomnia and fatigue. The physical examination reveals tenderness of the cervical paraspinal musculature and diminished cervical range of motion. There is diminished sensation of the bilateral C5, C6, and C7 dermatomes. There is diminished left shoulder range of motion and positive impingement signs. The diagnosis includes herniated cervical disc, cervical facet disease, left rotator cuff disease, and left middle finger sprain. Treatment to date has included medication management, modified duty with restrictions, X-ray of the left shoulder, electrodiagnostic studies, and acupuncture. The plan of care includes Sentra AM #60, Theramine #60, and Gabadone #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

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 (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic) Chapter, Medical food section.

Decision rationale: Sentra AM is a medical food containing choline and acetylcholine. 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. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Choline is a precursor of acetylcholine. 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. In this instance, the medical record does not show that the injured worker has liver deficiency. There is no indication the injured worker requires parenteral nutrition. Therefore, Sentra AM #60 is not medically necessary.

Theramine #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).

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

Decision rationale: Theramine is not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytrytophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The proposed mechanism of action is that it increases the production of serotonin, nitric oxide, histamine, and gamma-aminobutyric acid by providing these precursors. Per the Official Disability Guidelines, there is no role for for 5-hydorxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA as treatment for chronic pain. In this instance, the treating provider has prescribed Theramine to assist with pain and inflammation. Because the guidelines specifically do not recommend it, Theramine #60 is not medically necessary.

Gabadone #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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic) chapter, GABAdone and medical food sections.

Decision rationale: GABAdone is a Medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. There is no peer-reviewed research in humans to support the use of choline or glutamic acid for treatment of either anxiety or sleep disorder. There is inconclusive evidence for the use of 5-hydroxy tryptophan as a treatment for anxiety. GABA does not cross the blood-brain barrier so this supplement will not replace drugs that work in the brain by a GABA-related mechanism. There is no quality evidence to support use in anxiety. The GABAdone was prescribed to assist with the nutritional management of a sleep disorder. The injured worker does have an element of sleep apnea. However, GABAdone is not indicated for the management of sleep apnea. Therefore, GABAdone #60 is not medically necessary.