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| Case Number: | CM15-0196937 | | |
| Date Assigned: | 10/12/2015 | Date of Injury: | 10/01/2009 |
| Decision Date: | 11/18/2015 | UR Denial Date: | 09/18/2015 |
| Priority: | Standard | Application Received: | 10/06/2015 |

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 60 year old male, who sustained an industrial injury on 10-1-2009. The medical records indicate that the injured worker is undergoing treatment for hypertension with left ventricular hypertrophy. According to the progress report dated 8-27-2015, the injured worker presented with complaints of hypertension and acid reflux. The physical examination of the cardiovascular system reveals regular heart rate and rhythm, S1 and S2 with no rubs or gallops appreciated. Blood pressure is 139 over 78. The current medications are Lisinopril, Prilosec, Gaviscon, baby Aspirin, Lipitor, Hypertensa, Sentra AM, Sentra PM (since at least 1-15-2015), and Gabadone. Previous diagnostic studies include EKG, 2D echo, cardio-respiratory diagnostic testing, and impedance cardiography. Treatments to date include medication management. The original utilization review (9-18-2015) had non-certified a request for Hypertensa and Sentra PM.

IMR ISSUES, DECISIONS AND RATIONALES

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

90 Hypertensa - 4 bottles: 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 Chronic - Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical foods, pages 758-759.

Decision rationale: Hypertensa is a Medical Food product that provides amino acids, precursors to the neurotransmitters that have been depleted due to certain disease states or as a result of certain drug side effects. This Medical Food stimulates the body to produce the neurotransmitters that induce sleep, promote restorative sleep, and reduce snoring. Patients with sleep disorders frequently experience a nutritional deficiency of tryptophan and choline. Patients with sleep disorders frequently show reduced blood levels of serotonin and 5-hydroxytryptophan. Choline deficiency has also been associated with sleep disorders, particularly those associated with sleep apnea syndromes. Hypertensa is considered a medical food, used for the treatment of disease states with known nutritional deficiencies. Based on a review of the available medical reports, there is no evidence to suggest that this patient has any type of nutritional deficiency. According to the FDA, specific requirements for the safety or appropriate use of medical foods have not yet been established and Hypertensa is not FDA approved for any indication. Therefore, the use of any medical food or medical food combination would be considered experimental. Guidelines state this formulated food may be recommended for specific dietary management of a disease or condition for which distinctive nutritional requirements have been established by medical evaluation based on scientific principles. The provider had not documented the indication, clinical findings, diagnoses or medical necessity consistent with evidence-based, peer-reviewed, nationally recognized treatment guideline for this medical food. The 90 Hypertensa - 4 bottles is not medically necessary and appropriate.

60 Sentra PM - 3 bottles: 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 Control (Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medical Food, pages 758-760.

Decision rationale: Sentra is a medical food supplement in alternative medicine. MTUS is silent on its use; however, ODG states to be considered, the product must, at a minimum, meet the following criteria: (1) The product must be a food for oral or tube feeding; (2) The product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) The product must be used under medical supervision. Based on a review of the available medical reports, there is no evidence to suggest that this patient has any type of condition to warrant the investigational use of this supplement. Sentra is not medically necessary and appropriate. The provider has not provided any documentation of medical necessity consistent with evidence-based, peer-reviewed, nationally recognized treatment guideline for Sentra or any other alternative supplements nor has submitted reports identified any nutritional deficiency or medical conditions that would require nutritional supplementation as it relates to this patient's musculoskeletal injuries. Absent medical necessity, certification cannot be granted. The request for 60 Sentra PM - 3 bottles is not medically necessary and appropriate.