MAXIMUS Federal Services

| Case Number: | CM14-0041328 | | |
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| Date Assigned: | 06/30/2014 | Date of Injury: | 10/03/2008 |
| Decision Date: | 08/22/2014 | UR Denial Date: | 04/03/2014 |
| Priority: | Standard | Application Received: | 04/08/2014 |

## 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 Neuromusculoskeletal Medicine and is licensed to practice in Arizona. 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 48-year-old female who sustained a work related injury on October 3, 2008 as a result of unspecified right shoulder pain with a history of seizure disorder, memory and concentration following a fall at home on 10/03/2010 when she fell down and sustained blunt trauma to her head, suffering a skull fracture. On November 22, 2013, she underwent comprehensive medical screening. At that time she complained of right shoulder, elbow and wrist pain with associated numbness and tingling sensation in the hands and fingers. She has a history of and is currently experiencing sleep disturbance. With regards to her right shoulder pain she underwent a shoulder surgery for arthroscopic debridement of the acromioclavicular joint (AC) joint and distal clavicle resection on 01/03/2012 with post-operative physical therapy. She denied recent seizure, but has experienced a 10 pound weight gain since her injury. In dispute is a decision for topical cream, Sentra AM and Sentra PM.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Topical Cream (Flubiprofen 20%/Tramadol in Mediderm base) and (Gabapentin 10%/Amitriptyline 10%/Dextromethophan 10% in Mediderm base) 240 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines XX Pain Intervention and Treatments, page(s) 111-112 Page(s): 111-112.

**Decision rationale:** Topical analgesics (compounded) are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control medications of differing varieties and strengths. The addition of Gabapentin is not recommended as there is no peer reviewed literature support for its use. Because the patient does not have a documented complaint of neuropathic pain, failed antidepressant treatment trial and MTUS guideline not recommending use of Gabapentin in topical creams because of lack of peer reviewed literature, I find the request for the topical analgesic cream not medically necessary.

**Sentra AM #60 2 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.

**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:
http://ptloffice.com/downloads/marketing/Sentra_AM_Package_Insert_Sept_2012.pdf.

**Decision rationale:** Sentra AM is a specially formulated Medical Food product, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the dietary management of the metabolic processes associated with fatigue and cognitive disorders. (FCD) A critical component of the definition of a Medical Food is that the product must address the distinct nutritional requirements of a particular disease or condition. FDA scientists have proposed a physiologic definition of distinctive nutritional requirements as follows: the dietary management of patients with specific diseases requires, in some instances, the ability to meet nutritional requirements that differ substantially from the needs of healthy persons. For example, in establishing the recommended dietary allowances for general, healthy population, the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences recognized that different or distinctive physiologic requirements may exist for certain persons with special nutritional needs arising from metabolic disorders, chronic diseases, injuries, premature birth, other medical conditions and drug therapies. No evidence exists of nutritional deficiency as documented in the patient's records. In fact, it is documented that the patient has gained weight, negating the need for supplementation. The request is not medically necessary.

**Sentra PM #60 2 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.

**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:
http://ptloffice.com/downloads/marketing/Sentra_AM_Package_Insert_Sept_2012.pdf.

**Decision rationale:** Sentra PM is a specially formulated Medical Food product, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the dietary management of the metabolic processes associated with fatigue and cognitive disorders. (FCD)A critical component of the definition of a Medical Food is that the product must address the distinct nutritional requirements of a particular disease or condition. FDA scientists have proposed a physiologic definition of distinctive nutritional requirements as follows: the dietary management of patients with specific diseases requires, in some instances, the ability to meet nutritional requirements that differ substantially from the needs of healthy persons. For example, in establishing the recommended dietary allowances for general, healthy population, the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences recognized that different or distinctive physiologic requirements may exist for certain persons with special nutritional needs arising from metabolic disorders, chronic diseases, injuries, premature birth, other medical conditions and drug therapies. No evidence exists of nutritional deficiency as documented in the patient's records. In fact, it is documented that the patient has gained weight, negating the need for supplementation. The request is not medically necessary.