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| Case Number: | CM15-0094692 | | |
| Date Assigned: | 05/20/2015 | Date of Injury: | 12/05/2011 |
| Decision Date: | 06/25/2015 | UR Denial Date: | 05/04/2015 |
| Priority: | Standard | Application Received: | 05/15/2015 |

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 female, who sustained an industrial injury on 12/5/2011. Diagnoses have included lumbar radiculopathy, herniated lumbar disc, pain-related insomnia, myofascial syndrome and neuropathic pain. Treatment to date has included medication. According to the progress report dated 4/22/2015, the injured worker complained of severe headaches over the right eye and the right side of the head. She reported that Fioricet was ineffective. She was noted to have taken her last pain pill that morning. She rated her pain as 9/10 with medication and 10/10 without medication. Average pain was rated 9/10. Authorization was requested for Nattokinase.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nattokinase #20, No NDC #, no refills: 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) 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 Chapter, Medical food.

Decision rationale: The patient presents on 04/22/15 with severe headache located behind the right eye with a pain rating of 9/10. The patient's date of injury is 12/05/11. Patient has no documented surgical history directed at this complaint. The request is for Nattokinase #20, no NDC #, no refills, med food/supplement. The RFA is dated 04/22/15. Physical examination dated 04/22/15 does not include any physical findings, only a review of systems and current complaints. The patient is currently prescribed Xanax, Opana, Protonix, and Fioricet. Diagnostic imaging was not included. Patient's current work status is not provided. Regarding medical food, ODG states that it is intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must 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. 3. The product must be used under medical supervision. In this case, the provider is requesting a medical food, Nattokinase, a soybean derived nutritional supplement. This patient presents with chronic persistent headaches, however there is no discussion of GI complaints or other nutrition-related illness. ODG supports medical food, provided that the product is labeled for dietary management of a particular disorder and is utilized under medical supervision. There is no indication that the patient has been diagnosed with a nutritional disorder, or that said supplement will be administered under medical supervision, without such discussion, the request cannot be substantiated. Therefore, this request IS NOT medically necessary.