

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM14-0088272 | | |
| Date Assigned: | 07/23/2014 | Date of Injury: | 05/20/2008 |
| Decision Date: | 10/20/2014 | UR Denial Date: | 05/30/2014 |
| Priority: | Standard | Application Received: | 06/12/2014 |

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 Anesthesiology, has a subspecialty in Pain Management, and is licensed to practice in California. 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:

According to the records made available for review, this is a 49-year-old female with a 5/20/08 date of injury. At the time (5/28/14) of the Decision for Gaboxetine and Sentra PM X 60, there is documentation of subjective (low back pain and bilateral leg symptoms) and objective (decreased lumbar spine range of motion, tenderness over the lumbosacral junction, and positive straight leg raise) findings, current diagnoses (degenerative disc disease, lumbosacral spondylosis, sciatica, and arthrodesis), and treatment to date (medications). Regarding Sentra PM, there is no documentation identifying that the product is a food for oral or tube feeding; that is labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and that is used under medical supervision.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gaboxetine: 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

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://nutrientpharmacology.com/PDFs/copacks/GABAdone-Gaboxetine_Fluoxetine-co_pack.pdf

Decision rationale: An online search identifies Gaboxetine as a compound medication kit that includes Fluoxetine and GABAdone. ODG identifies that GABAdone is a medical food consisting of a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan and GABA, intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep, and reducing snoring in patients who are experiencing anxiety related to sleep disorders. In addition, ODG identifies that GABAdone is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Gaboxetine is not medically necessary.

Sentra PM X 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, Pain Chapter

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 Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20; and <http://www.ptlcentral.com/medical-foods-products.php>

Decision rationale: An online source identifies Sentra PM as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the nutritional management of the altered metabolic processes of sleep disorders associated with depression. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that the product must be a food for oral or tube feeding; must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of degenerative disc disease, lumbosacral spondylosis, sciatica, and Arthrodesis. However, there is no documentation identifying that the product is a food for oral or tube feeding; that is labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and that is used under medical supervision. Therefore, based on guidelines and a review of the evidence, the request for Sentra PM X 60 is not medically necessary.