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| Case Number: | CM15-0164072 | | |
| Date Assigned: | 09/01/2015 | Date of Injury: | 09/17/2013 |
| Decision Date: | 10/23/2015 | UR Denial Date: | 07/28/2015 |
| Priority: | Standard | Application Received: | 08/21/2015 |

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 33 year old male who sustained an industrial injury on 9-17-13. The injured worker was diagnosed as having major depressive disorder, post-traumatic stress disorder, anxiety disorder, adjustment disorder due to chronic pain with anxiety, depressive disorder and insomnia. Currently, the injured worker reported anxiety and trouble sleeping at night. Previous treatments included selective serotonin reuptake inhibitor, benzodiazepine, and medical food. Work status was not documented. The injured workers pain level was not documented. Physical examination was not documented. The plan of care was for Sentra AM quantity of 60, Sentra PM Quantity of 60 and Gabadone quantity of 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, Pain.

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 under Medical Foods.

Decision rationale: The patient presents with bilateral knee pain. He continues to experience stress. The request is for sentra AM #60. The request for authorization is not provided. MRI of the right knee, 01/26/15, shows possible occult type-tear involving the posterior horn of the medial meniscus at the periphery; mild irregular apical chondromalacia patella. MRI of the left knee, 01/23/15, shows possible distal anterior cruciate ligament sprain. Physical examination reveals patellar grinding is positive bilaterally. Tenderness is elicited along the medial joint line on the right. There is tenderness noted over the patella over the left knee. McMurray's test is positive bilaterally. The patient only takes the medication on an as needed basis, which does provide good pain relief. Patient stable with medication. Patient feels medication is wearing off too quickly. Patient has trouble sleeping at night. Pt has some anxiety developing secondary to unwanted news about his injuries. Recommend for the patient to continue with a home exercise program. Per progress report dated 07/09/15, the patient remains temporarily totally disabled. ODG, Pain Chapter under Medical Foods states: "medical food: 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." Per progress report dated 07/20/15, treater's reason for the request is "Cognitive Disorder & Fatigue." Patient has been prescribed Sentra AM since at least 04/23/15. Sentra AM is a medical food prescribed for sleep issues, fibromyalgia, and cognitive decline. In this case, the patient has a diagnosis of major depressive disorder, posttraumatic stress disorder, and insomnia, but provided medical records do not indicate that the patient has been diagnosed with a nutritional disorder or that supplement will be administered under medical supervision. Furthermore, there is no mention of choline deficiency secondary to liver deficiency in provided reports. Since use of Choline is not indicated for this patient, the request for Sentra AM cannot be recommended. Therefore, the request IS NOT medically necessary.

Sentra PM #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.

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 under Medical Foods Pain Chapter under Sentra PM.

Decision rationale: The patient presents with bilateral knee pain. He continues to experience stress. The request is for Sentra PM #60. The request for authorization is not provided. MRI of the right knee, 01/26/15, shows possible occult type-tear involving the posterior horn of the medial meniscus at the periphery; mild irregular apical chondromalacia patella. MRI of the left knee, 01/23/15, shows possible distal anterior cruciate ligament sprain. Physical examination

reveals patellar grinding is positive bilaterally. Tenderness is elicited along the medial joint line on the right. There is tenderness noted over the patella over the left knee. McMurray's test is positive bilaterally. The patient only takes the medication on an as needed basis, which does provide good pain relief. Patient stable with medication. Patient feels medication is wearing off too quickly. Patient has trouble sleeping at night. Pt has some anxiety developing secondary to unwanted news about his injuries. Recommend for the patient to continue with a home exercise program. Per progress report dated 07/09/15, the patient remains temporarily totally disabled. ODG Guidelines, Pain Chapter under Medical Foods states: "Medical food: 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...Not recommended for chronic pain." ODG Guidelines, Pain Chapter under Sentra PM states: "Sentra PM is a medical food from Targeted Medical Pharma Inc., Los Angeles, California, intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan." ODG further states that for choline, "there is no known medical need for choline supplementation." For glutamic acid, "this supplement is used for treatment of hypochlorhydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer, and critical illnesses. It is generally used for digestive disorders and complementary medicine." For 5-hydroxytryptophan, "the supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has been found to be effective for depression." Per progress report dated 07/20/15, treater's reason for the request is "Sleep/Depression." Patient has been prescribed Sentra PM since at least 04/23/15. In this case, the treating physician has dispensed Sentra PM, which consists of choline bitartrate, glutamate, and 5-hydroxytryptophan. Both choline and glutamic acid are not supported by ODG Guidelines. The treater has not provided a medical rationale to prescribe a medical food that contains ingredients not supported by ODG. Therefore, the request 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, Pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter under GABA done.

Decision rationale: The patient presents with bilateral knee pain. He continues to experience stress. The request is for Gabadone #60. The request for authorization is not provided. MRI of the right knee, 01/26/15, shows possible occult type-tear involving the posterior horn of the medial meniscus at the periphery; mild irregular apical chondromalacia patella. MRI of the left knee, 01/23/15, shows possible distal anterior cruciate ligament sprain. Physical examination reveals patellar grinding is positive bilaterally. Tenderness is elicited along the medial joint line on the right. There is tenderness noted over the patella over the left knee. McMurray's test is

positive bilaterally. The patient only takes the medication on an as needed basis, which does provide good pain relief. Patient stable with medication. Patient feels medication is wearing off too quickly. Patient has trouble sleeping at night. Pt has some anxiety developing secondary to unwanted news about his injuries. Recommend for the patient to continue with a home exercise program. Per progress report dated 07/09/15, the patient remains temporarily totally disabled. MTUS and ACOEM guidelines are silent with regards to this product. However, ODG Guidelines, Pain (Chronic) Chapter under GABAdone Section states, "Not recommended. GABAdone is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is 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." Per progress report dated 07/20/15, treater's reason for the request is "Sleep/Depression." Patient has been prescribed GABAdone since at least 04/23/15. However, ODG guidelines state, "Not recommended. GABAdone is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is 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." ODG guidelines do not support the use of GABAdone for chronic pain or for sleep aid. Therefore, the request IS NOT medically necessary.