

Case Number:	CM13-0070119		
Date Assigned:	01/03/2014	Date of Injury:	05/27/2011
Decision Date:	04/30/2014	UR Denial Date:	11/25/2013
Priority:	Standard	Application Received:	12/24/2013

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 Physical Medicine and Rehabilitation, has a subspecialty in Pediatric Rehabilitation Medicine and is licensed to practice in Texas. 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:

The patient is a 69-year-old male who reported an injury on 05/27/2011. The mechanism of injury was not provided in the medical records. The patient was diagnosed with diabetes mellitus without mention of complication, type 2 or unspecified type. The patient's symptoms included right shoulder pain of 7/10, low back pain rated at 6-7/10, and left knee pain rated at 7/10. Upon examination of the cervical spine, range of motion was limited and painful upon flexion, extension, right rotation, left rotation, right lateral flexion, and left lateral flexion. Upon examination of the right shoulder, range of motion was limited and painful. Upon examination of the lumbosacral spine, range of motion was limited and painful. Upon examination of the bilateral knees, range of motion was limited and painful upon flexion and extension. The patient was prescribed medications for pain and diabetes in order to alleviate his symptoms. The provider requested Sentra PM 60 tablets, Trepadone 90 tablets, and Theramine 60 tablets on 10/14/2013 to aid in reducing the patient's symptoms.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE SENTRA PM #60 (ONE (1) BOTTLE) FOR DOS 10/14/2013: 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), Pain, Sentra PM / 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, Sentra PM / Medical Food

Decision rationale: According to the Official Disability Guidelines, medical food is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by a medical evaluation. 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. The guidelines further state, Sentra PM is intended for use in management of sleep disorders associated with depression. Sentra PM is a proprietary blend of choline bitartrate, glutamate, and 5-Hydroxytryptifan. Additionally, there is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. As the guidelines state there is no known medical need for a choline supplementation and the documentation submitted for review failed to provide evidence of specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, the request is not supported. Additionally, the request did not indicate what frequency at which the medication was prescribed in order to determine the necessity. Given the above, the request for Sentra PM 60 tablets (1 bottle) is non-certified.

**RETROSPECTIVE TREPADONE TABLETS #90 (ONE (1) BOTTLE) FOR DOS
10/14/2013: 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), Pain, Trepadone / 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, Trepadone / Medical food

Decision rationale: According to the Official Disability Guidelines, medical food is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by a medical evaluation. 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. The guidelines further state Trepadone is intended for use in the management of joint disorders associated with pain and inflammation. Trepadone includes a blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gamma aminobutyric. Additionally, there is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. As the guidelines state there is no known

medical need for a choline supplementation and the documentation submitted for review failed to provide evidence of specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, the request is not supported. Additionally, the request did not indicate what frequency at which the medication was prescribed in order to determine the necessity. Given the above, the request for Trepadone 90 tablets (1 bottle) is non-certified.

**RETROSPECTIVE THERAMINE TABLETS #60 (TWO (2) BOTTLES) FOR DOS
10/14/2013: 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), Pain, Theramine®/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, Theramine®/Medical food

Decision rationale: According to the Official Disability Guidelines, medical food is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by a medical evaluation. 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. The guidelines further state Theramine is not recommended. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Theramine is a proprietary blend of gamma-aminobutyric acid (GABA) and choline bitartrate, L-arginine, and L-serine. The guidelines further state there is no high quality peer reviewed literature that suggests that GABA is indicated. Additionally, there is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. As the guidelines state there is no known Final Determination Letter for IMR Case Number [REDACTED] medical need for a choline supplementation and the documentation submitted for review failed to provide evidence of specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, the request is not supported. Additionally, the request did not indicate what frequency at which the medication was prescribed in order to determine the necessity. Therefore, the request is not supported. Given the above, the request for Theramine 60 tablets (2 bottles) is non-certified.