

Case Number:	CM14-0148239		
Date Assigned:	09/18/2014	Date of Injury:	09/10/2012
Decision Date:	10/21/2014	UR Denial Date:	08/11/2014
Priority:	Standard	Application Received:	09/11/2014

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 Tennessee. 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 45-year-old male with a 9/10/12 date of injury. A specific mechanism of injury was not described. According to a progress report dated 9/4/14, the patient complained of bilateral knee pain radiating down to the feet, rated as a 7/10. He complained of right hand pain with numbness rated as a 7/10 and lumbar spine pain with numbness rated as a 6/10. Medications and therapy help reduce his pain. Objective findings: tenderness of left knee and decreased range of motion, tenderness to abdomen below umbilicus, tenderness to lumbar spine with decreased range of motion and muscle spasm. Diagnostic impression: left knee meniscal tear, lumbar spine disc protrusion, ventral hernia, myospasm. His treatment to date includes medication management, activity modification, chiropractic care, and interferential unit. A UR decision dated 8/11/14 denied the requests for Sentra and Theramine. Regarding Sentra, the claimant does not have any documented choline deficiency or diagnoses to support the medical necessity of this medical food. Regarding Theramine, since treatment guidelines do not support this type of product until higher quality studies of the ingredients can be accomplished, the request is considered not medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra, QTY: 60: Upheld

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

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 Other Medical Treatment Guideline or Medical Evidence: <http://www.ptlcentral.com/medical-foods-products.php>

Decision rationale: The CA MTUS does not address this issue. The FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. According to an online search, Sentra is a specially formulated prescription only Medical Food, consisting of a proprietary formulation of amino acids (choline and acetylcarnitine) and polyphenol ingredients in specific proportions, for the dietary management of the metabolic processes associated with fatigue and cognitive disorders. In the reports reviewed, there is no documentation of choline deficiency in this patient. In addition, there is no rationale or indication provided for the treatment with Sentra, despite guideline support. Therefore, the request for Sentra, QTY:60 was not medically necessary.

Theramine, QTY: 90: Upheld

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

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

Decision rationale: The CA MTUS does not address this issue. ODG states that Theramine is not recommended. There is no high quality peer-reviewed literature that suggests that GABA is indicated; There is no known medical need for choline supplementation; L-Arginine is not indicated in current references for pain or inflammation; L-Serine is not indicated. In a manufacturer study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. A specific rationale identifying why Theramine would be required in this patient despite lack of guideline support was not provided. Therefore, the request for Theramine, QTY: 90 was not medically necessary.