

Case Number:	CM14-0010392		
Date Assigned:	02/21/2014	Date of Injury:	11/12/1997
Decision Date:	07/17/2014	UR Denial Date:	01/10/2014
Priority:	Standard	Application Received:	01/27/2014

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 Occupational Medicine 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:

This is a 71-year-old female with an 11/12/97 date of injury. The patient worked as a processing technician and sustained injuries while performing usual/customary duties. In a progress report dated 11/22/13, it was noted that the patient's symptoms included continued total body pain, chronic fatigue, and sleep problems. The patient had right-sided abdominal pain over the skin. Objective findings were essentially normal, except for greater than 12 trigger points with tenderness. Diagnostic impression: myalgia, myositis, and chronic depressive personality disorder. The patient's treatment to date included medication management and activity modification. A UR decision dated 1/11/14 denied the request for Sentraflox AM. The duration and frequency was unknown for back and fibromyalgia. This request is a medical food that contains Fluoxetine and Sentra AM. The MTUS does not apply. The ODG quoting the FDA specifically states that to be considered, the product must be labeled for dietary management of a specific medical disorder, disease, or condition.

IMR ISSUES, DECISIONS AND RATIONALES

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

SENTRAFLOX AM DURATION AND FREQUENCY UNKNOWN FOR BACK AND FIBROMYALGIA: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Non-MTUS Official Disability Guidelines (ODG), Pain Chapter, Medical Food and Other Clinical Protocol and Non-MTUS website US

National Institutes of Health (NIH) National Library of Medicine (NLM) PubMed, 2012, www.ncbi.nlm.nih.gov/pubmed/, and Non-MTUS website Physician Therapeutics, www.tmedpharma.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Non-MTUS Official Disability Guidelines (ODG), Pain chapter.

Decision rationale: The California MTUS does not address this issue. However, the FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. In addition, there is no rationale or indication provided for the treatment with the requested medications. Sentraflox AM is a combination product that contains Fluoxetine and Choline, which is considered a medical food. Choline is a precursor of acetylcholine. 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. The guidelines state that in order 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. There is no documentation as to how Choline would be beneficial to the patient and that there is a nutritional deficiency in the patient. Furthermore, the quantity requested is not noted. In addition, this is a combination of Fluoxetine and Choline; there is no rationale as to why this product would be more beneficial than taking the medications separately. Therefore, the request for Sentraflox AM and fibromyalgia was not medically necessary.