

Case Number:	CM14-0065475		
Date Assigned:	07/11/2014	Date of Injury:	03/11/2013
Decision Date:	09/10/2014	UR Denial Date:	04/18/2014
Priority:	Standard	Application Received:	05/08/2014

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 patient is a 53 year old female employee with date of injury of 3/11/2013. A review of the medical records indicate that the patient is undergoing treatment for: PTSD (post traumatic stress disorder); Major Depression, single episode, Moderate; Generalized Anxiety Disorder; Pain Disorder associated with both psychological factors and a general medical condition (condition not stated) (3/11/2013). Subjective complaints include anxiety and inexplicable worrying, nightmares with recall of traumatic events, difficulty sleeping (10/8/2013). Patient does refer to decreased depression and anxiety as long as patient keeps taking her medications (8/7/2013, 9/4/2013). Additional findings include "I'm still having depression, panic episodes and poor sleep". Medical records indicate that affect is appropriate to mood and moderately depressed and anxious (10/8/2013), migraines occur about once a month, decreased sex drive, and has difficulty sleeping at night (she wakes up for at least an hour two to three times each night (10/10/2013)). Treatment has included psychotherapy sessions dating back to May 2013 (10/8/2013). Medications include Topamax 50mg (for migraine prevention), Lexapro 20mg, Klonopin 1mg, Trazodone 50mg for sleep, Xanax and Vistaril for sleep (10/8/2013) and Enlyte (which had not been approved (3/11/2013 and 5/8/2014), Entyre 15mg #30 on 4/14/2014 , Cognitive Behavior Therapy 2/month, self-defense training (8/1/2013). The utilization review dated 4/18/2014 non-certified of Enlyte 16mg due to lack of support from guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

ENLYTE 16MG: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM, 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) Chronic Pain, Medical foods - Mental Illness & Stress, Folate and Other Medical Treatment Guideline or Medical Evidence: <http://www.enlyterx.com/About%20Enlyte/>.

Decision rationale: Enlyte is a "is a natural, pure prescription multivitamin that contains DeltaFolate TM (L-methylfolate, folinic acid, and folic acid)" and is intended for symptomatic relief of depression, per the manufacturer's insert. MTUS and ACOEM are silent concerning Enlyte. ODG does not recommend for or against Folate, which is a major component of Enlyte, in cases of mental illness. ODG states regarding folate, "Under study. The limited available evidence suggests folate may have a potential role as a supplement to other treatment for depression. It is currently unclear if this is the case both for people with normal folate levels, and for those with folate deficiency." In addition ODG states that a medical food is "Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered eternally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by 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 medical documents do not indicate the distinctive nutritional requirement for which Enlyte would be used. Folate is a major component of Enlyte, however, the medical records do not indicate folate deficiency. As such, the request for Enlyte 16mg is not medically necessary.