

Case Number:	CM15-0052240		
Date Assigned:	03/25/2015	Date of Injury:	01/09/2014
Decision Date:	05/01/2015	UR Denial Date:	02/26/2015
Priority:	Standard	Application Received:	03/19/2015

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: New Jersey

Certification(s)/Specialty: Family Practice

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 53 year old female, who sustained an industrial injury on January 9, 2014. She has reported neck pain, shoulder pain, elbow pain, hand pain, back pain, bilateral knee pain, depression, and anxiety. Diagnoses have included cervical spine strain/sprain, lumbar spine strain/sprain, lumbar spine radiculitis, right knee pain, right knee strain, left knee pain, left knee strain/sprain, and adjustment disorder due to chronic pain with mixed anxiety and depressed mood. Treatment to date has included medications, back brace, chiropractic treatment, psychiatric care, and imaging studies. A progress note dated January 20, 2015 indicates a chief complaint of depression, chronic pain, sleep difficulties, anxiety, and fatigue. The treating physician documented a plan of care that included continuation of medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Continued use of 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 (ODG), Pain, Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain section, Medical food AND Physician Therapeutics, Sentra AM (<http://www.ptlcentral.com/medical-foods-products.php>).

Decision rationale: Sentra AM is a medical food product, which contains various ingredients including choline, arginine, GABA, histidine, tryptophan, and serine, and is marketed for the treatment of fatigue and cognitive disorders. The MTUS is silent regarding Sentra AM or its ingredients individually. The ODG, however, states that medical food may be recommended in certain situations where there is a distinctive nutritional requirement. Choline, the primary ingredient in Sentra AM is only recommended for long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency, and is not generally recommended yet for other indications. Choline and these other amino acids are found in foods, which can be prescribed to patients as well, so there is no need for a specific product for most patients. In the case of this worker, Sentra AM was requested to be taken, however, due to lack of evidence of a nutrient deficiency, the Sentra AM will be considered not medically necessary.

Continued use of Theramine #90: 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, Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain section, Theramine.

Decision rationale: The MTUS Guidelines are silent when it comes to use of Theramine. Theramine is a medical food product that includes a variety of amino acids, GABA, 5-HTP, and other ingredients, and is used in the management of pain syndromes. The ODG states that Theramine is not recommended as there is no high quality peer-reviewed literature that shows that these ingredients are effective. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended, according to the ODG. In the case of this worker, Theramine was requested to be taken, however, due to the ODG not recommended use and due to lack of evidence of a nutrient deficiency, the Theramine will be considered not medically necessary.

Continued use of Gaboxetine (gabadone & fluoxetine): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SSRIs (selective serotonin reuptake inhibitors) Page(s): 107. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain section, Medical Food AND Mental Illness section, Fluoxetine.

Decision rationale: The MTUS is silent regarding Gaboxetine, which is a combination drug product which contains fluoxetine and Gabadone, a medical food product. The ODG, however, states that fluoxetine is recommended as a first-line treatment option for major depressive disorder and PTSD. Gabadone is a medical food product which includes the following ingredients: 5-Hydroxytryptophan, choline bitartrate, gamma aminobutyric acid, cocoa extract, l-glutamic acid, whey protein, griffonia extract, valerian root, acetyl l-carnitine, ginkgo biloba, and grape seed extract, which are all generally recognized as safe. Gabadone is formulated for the treatment of sleep disorders. The MTUS is silent in regards to Gabadone. The ODG states that some individual medical foods may be recommended in special circumstances where there is a clear nutritional deficiency. However, Gabadone is not recommended by the ODG. None of these ingredients found in Gabadone, however, are considered first-line therapy for sleep disorders, mostly due to limited quality studies. Since the specific product, Gabadone, includes multiple ingredients that together have even less evidence of benefit and safety, it is unreasonable to suggest this as an approved product for recommendation. In the case of this worker, Gaboxetine was requested to be taken, however, due to lack of evidence of a nutrient deficiency, and due to the worker being also recommended Fluoxetine separately from this request (redundancy), the Gaboxetine will be considered not medically necessary.