

Case Number:	CM15-0005789		
Date Assigned:	01/26/2015	Date of Injury:	09/10/2006
Decision Date:	03/17/2015	UR Denial Date:	12/13/2014
Priority:	Standard	Application Received:	01/12/2015

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, Michigan, California
 Certification(s)/Specialty: Neurology, Neuromuscular Medicine

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 51 year old female, who sustained an industrial injury on 9/01/2006. The mechanism of injury has not been provided with the clinical documentation submitted for review. The diagnoses include right shoulder impingement status post subacromial decompression (6/01/2010), left shoulder impingement syndrome, bilateral carpal tunnel syndrome status post failed right side release, psychological trauma and depression, cervical spine pathology with large disc herniation, right ring finger trigger finger status post release, migraines, adnominal pain, gastroesophageal reflux disease (GERD), gastric ulcer, and reflux esophagitis. Currently, the IW complains of uncontrolled blood glucose and worsened gastroesophageal reflux symptoms. She reports migraine headaches and forgetfulness. Dysphagia and shortness of breath are still bothersome. Sleep is still problematic. She states that she sleeps three hours nightly and wakes up frequently. Objective findings revealed an anxious affect. There is a soft abdomen with normoactive bowel sounds. There is diffuse 3+ tenderness to palpation over the entire abdomen. There is positive guarding, unable to assess for hepatosplenomegaly. On 12/13/2014, Utilization Review non-certified a request for Sentra PM noting that medical foods are not indicated for chronic pain per the guideline recommendations. The ODG was cited. On 1/12/2015, the injured worker submitted an application for IMR for review of Sentra PM.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra PM #60/three bottles: 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), Medical Foods

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Food
<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Medicalfood>

Decision rationale: According to ODG guidelines, medical food. “ Recommended as indicated below. 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 entirely 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. See Food labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule (56 FR 60366 at 60377, November 27, 1991). Medical foods are exempted from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343 (q) (5) (A) (iv)). Medical foods do not have to be registered with the FDA. (CFsAN, 2008) Current available medical food products: Choline: 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. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high-dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. (AltMedDex, 2008) (Clinical Pharmacology, 2008).Glutamic Acid: This supplement is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine. (AltMedDex, 2008) (Lexi-Comp, 2008).5-hydroxytryptophan: This supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome. (De Benedittis, 1985) (Klarskov, 2003) (AltMedDex, 2008) (Lexi-Comp, 2008).Gamma-aminobutyric acid (GABA): This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse

reactions associated with treatment include hypertension, increased heart rate and anxiety. Dose reductions are indicated for a creatinine clearance > 60 ml/min. (AltMedDex, 2008) In this low quality RCT, with no description for the actual sleep disorder, an amino acid preparation containing both GABA and 5-hydroxytryptophan reduced time to fall asleep, decreased sleep latency, increased the duration of sleep, and improved quality of sleep. (Shell, 2009).L-Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement. L-Arginine: This supplement is not indicated in current references for pain or "inflammation." It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome. (AltMedDex, 2008) (CFSSAN, 2008) (Clinical Pharmacology, 2008) (Lexi-Comp, 2008) (Micromedex, 2008).Honey & cinnamon: Recommended as an option for arthritis pain. See separate listing for Honey & cinnamon.Limbrel (flavocoxid): Under study as an option for arthritis in patients at risk of adverse effects from NSAIDs, with recent evidence that Limbrel is capable of causing acute liver injury and should be used with caution. (Chalasanani, 2012).See separate listing for Limbrel (flavocoxid/ arachidonic acid). See also NSAIDs, GI symptoms & cardiovascular risk; & NSAIDs, hypertension and renal function. See also Compound drugs; Co-pack drugs; Physician-dispensed drugs; Repackaged drugs. For brand names of medical foods and their respective ingredients, see Deplin (L-methylfolate); GABAdone; Sentra PM; Theramine; Trepadone; & UltraClear.” There are no controlled studies supporting the safety and efficacy for the use of Sentra for the treatment of pain. Furthermore, there no documentation that the patient suffered from a nutrition deficit that requires the use of Sentra. Based on the above, the prescription of Sentra is not medically necessary.

ASA (Aspirin) 81 mg #45 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation The Guide to Cardiology, 4th Edition, pages 155-170

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Aspirin

Decision rationale: According to ODG guidelines, <Recommended. See Nonprescription medications; & Medications for acute pain (analgesics). Usual Adult Dose for Pain: 325 to 650 mg every 4 hours as needed, up to 3 grams per day in divided doses (spondyloarthropathies may require up to 4 grams per day in divided doses). (FDA, 2012)>. The request is for low dose of Aspirin which has no antalgic effect but an anti platelet aggregation effect which is no clearly indicated in this case. Therefore, the prescription of ASA (Aspirin) 81 mg #45 with 2 refills is not medically necessary.