

<b>Case Number:</b>	CM15-0051404		
<b>Date Assigned:</b>	03/24/2015	<b>Date of Injury:</b>	04/26/2004
<b>Decision Date:</b>	05/01/2015	<b>UR Denial Date:</b>	02/13/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/18/2015

### 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 female, who sustained an industrial injury on 4/26/2004. The details regarding the initial injury were not included in the medical records submitted for this review. Diagnoses include post laminectomy syndrome. She is status post lumbar surgery. Treatments to date include medication therapy, home exercise and home aquatic therapy. Currently, she complained of chronic back and leg pain rated 7/10 VAS. On 1/30/15, the physical examination documented she ambulated with a walker with antalgic gait, positive left side straight raise leg test, and muscle spasm and guarding of the lumbar spine. The plan of care included continuation of medication therapy and a replacement walker due to broken parts on the current walker.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cymbalta 30mg Qty: 30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
 SPECIFIC ANTIDEPRESSANTS Page(s): 15-16.

**Decision rationale:** Cymbalta is FDA approved for diabetic neuropathy. It is also used off label for neuropathic pain and radiculopathy. There is no high quality evidence to support its use for lumbar radiculopathy. There is no clear evidence that the patient have diabetic neuropathy. A prolonged use of Cymbalta in this patient can not be warranted without continuous monitoring of its efficacy. Therefore, the request of 30 Cymbalta 30mg is not medically necessary.

**Sentra PM medical food Qty: 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 chapter.

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

**Decision rationale:** According to ODG guidelines, medical food. 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. (Chalasani, 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 is 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 PM #60 is not medically necessary.