

Case Number:	CM15-0009883		
Date Assigned:	01/27/2015	Date of Injury:	06/08/2012
Decision Date:	03/25/2015	UR Denial Date:	12/18/2014
Priority:	Standard	Application Received:	01/16/2015

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: Texas, California
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:

This is a 55 year old female patient, who sustained an industrial injury on 06/08/2012. The diagnoses have included cervical spine spondylosis with degenerative disc disease; thoracic spondylosis; lumbar sprain/strain; and lumbar spondylosis. She sustained the injury due to hitting her right hand, wrist and index finger against head of sewing machine. Per the progress note from the treating physician, dated 09/22/2014, she had complaints of an exacerbation of pain to the right forearm, left forearm, lower back, neck, and left shoulder; headaches; lack of sleep; and requested home care assistance. Objective findings included tenderness to palpation over the paracervical and sternocleidomastoid muscles bilaterally; tenderness to palpation over the supraspinatus and paralumbar muscles; tenderness to palpation over the acromioclavicular joint and rotator cuff muscles bilaterally; and right wrist tenderness to palpation. Per the note dated 8/7/2014, she had gastric upset, sleep disturbances and shortness of breath. The medications list includes xanax, Naprosyn and Omeprazole. Her surgical history includes appendectomy. She has undergone endoscopy and colonoscopy on 5/29/2013. She has had EMG/NCS on 8/15/2014; MRI left shoulder on 8/17/2014. She has had acupuncture sessions, chiropractic sessions, and physical therapy for this injury. The treatment plan has included continuing medications; refer patient for home health care assessment; advised to see her private medical doctor regarding her metabolic problems; home exercise program; and follow-up evaluation. On 12/18/2014 Utilization Review noncertified a prescription for Apptrim-D #120 3 Bottles. The ODG Pain: Medical Food was cited. Utilization Review noncertified a prescription for Hypertensa #90 3 Bottles. The ODG Pain: Medical Food was cited. On 01/13/2015, the injured worker submitted

an application for IMR for review of a prescription for Apptrim-D #120 3 Bottles; and a prescription for Hypertensa #90 3 Bottles.

IMR ISSUES, DECISIONS AND RATIONALES

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

Apptrim-D #120 3 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) Pain; Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chapter: Pain (updated 03/18/15) Medical food

Decision rationale: Request: Apptrim-D #120 3 bottles Apptrim-D is a medical food which contains L-tyrosine, L-glutamate, 5-hydroxytryptophan, L-histidine, L- serine, choline bitartrate, whey protein hydrolysate, cocoa Extract, Grape Seed Extract. Apptrim D is used for the dietary management of obesity associated with metabolic syndrome. California Medical Treatment Utilization Schedule (MTUS) does not address this request. According to the ODG guidelines, Medical food is, "a food which is formulated to be consumed or administered enterally 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." ODG quoting the FDA specifically states "To be considered the product must, at a minimum, meet the following criteria: (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements." Per the ODG, 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. The response to non pharmacological measures for treatment of insomnia and obesity is not specified in the records provided. There is no documented dietary deficiency of any of the components of this product. Therefore, there is no medical necessity for any medication containing these food supplements. These products still have limited scientific evidence for efficacy and safety profile for the management of pain. The medical necessity of Apptrim-D #120 3 bottles is not fully established for this patient at this time.

Hypertensa #90 3 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) Pain; Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chapter: Pain (updated 03/18/15) Medical food

Decision rationale: Request: Hypertensa #90 3 bottles Hypertensa is a medical food which contains L-Arginine, L-Glutamine, Histidine (as Histidine HCL), Choline Bitartrate, Dextrose, Cinnamon, Ginkgo Biloba, Grape Seed Extract, Caffeine, Cocoa, Ginseng. California Medical Treatment Utilization Schedule (MTUS) does not address this request. According to the ODG guidelines, Medical food is, "a food which is formulated to be consumed or administered enterally 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. ODG quoting the FDA specifically states "To be considered the product must, at a minimum, meet the following criteria: (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements" Per the ODG, 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)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) The response to non pharmacological measures for treatment of hypertension is not specified in the records provided. There is no documented dietary deficiency of any of the components of this product. Therefore, there is no medical necessity for any medication containing these food supplements. These products still have limited scientific evidence for efficacy and safety profile for the management of pain. The medical necessity of Hypertensa #90 3 bottles is not fully established for this patient at this time.

