

Case Number:	CM15-0113010		
Date Assigned:	06/19/2015	Date of Injury:	08/07/2012
Decision Date:	07/27/2015	UR Denial Date:	06/01/2015
Priority:	Standard	Application Received:	06/11/2015

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 32 year old female patient who sustained an industrial injury on 08/07/2012. The accident is described as while working one week prior to 08/07/2012, she experienced pain involving the cervical spine, thoracic spine, bilateral upper extremities, bilateral lower extremities while performing normal job duties and without specific trauma. The diagnoses include cervical disc protrusion; right shoulder bicipital tenosynovitis; right wrist/hand sprain/strain; bilateral knee medial meniscus tear, and bilateral knee chondromalacia patella. Per the doctor's note dated 2/24/2015, she had complaints of neck pain with radiation to the bilateral upper extremities; right shoulder pain and right wrist pain with tingling and numbness. The physical examination revealed cervical spine- range of motion flexion 40, extension 40, right/left rotation 70/70 and right/left lateral bending 35/35 degrees bilaterally, tenderness over the bilateral trapezius with spasm; right shoulder- mild decreased range of motion; right wrist- range of motion- flexion 50, extension 40, radial/ulnar deviation 10/15 degrees and positive Phalen's test. The medications list includes Ibuprofen, Omeprazole, Terocin patch and topical compound creams. Per the primary treating office visit dated 09/22/2014 she had complaints of frequent neck pain radiating to bilateral upper extremities with numbness and tingling. There is also frequent right shoulder pain, right wrist/hand pain with parasthesia's, and constant bilateral knee pain. Without the medication the pain is rated an 8 out of 10 in intensity and with medication use it's rated a two in intensity. She states getting relief from the topical cream. The initial report of illness dated 09/04/2012 reported subjective complaint of bilateral lower extremities, bilateral wrists/hands, bilateral knees, bilateral ankles, insomnia, and depression. Objective findings showed right shoulder, right wrist with limited range of motion. She was made temporarily totally disabled through 10/19/2012. On both 09/28/2013, and 10/24/2013 the patient underwent a sleep study testing.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabadone #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. 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 Official Disability Guidelines (ODG) Chapter: Pain (updated 07/15/15) Medical food.

Decision rationale: Gabadone is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. Per the cited guidelines, "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 greater than 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)."Therefore these products still have limited scientific evidence for efficacy and safety profile for the management of pain. ACOEM and CA MTUS do not address these medications. The contents of these medical food products are not recommended by ODG. According to the ODG guidelines, Medical food is 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 are 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. The response to other pharmacological measures for treatment of pain is not specified in the records provided. There is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications. 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 Gabadone #60 is not established at this time.

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 chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 07/15/15) Medical food.

Decision rationale: Sentra AM provides the amino acid precursors for the neurotransmitter precursor acetylcholine. Sentra AM is designed to provide dietary management for conditions associated with fatigue and cognitive dysfunction. Sentra is a patented blend of neurotransmitters and neurotransmitter precursors (choline bitartrate and glutamate); activators of precursor utilization (acetyl-L-carnitine, glutamate, and cocoa powder); polyphenolic antioxidants (grape-seed extract, hawthorn berry, cocoa powder); an amino acid uptake stimulator (gingko biloba); an adenosine antagonist (cocoa powder); and an inhibitor of the attenuation of neurotransmitter production associated with precursor administration (grape-seed extract). Per the manufacturers, "Sentra is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory." ACOEM and CA MTUS do not address these medications. Per ODG guidelines, "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." Glutamic Acid: This product is used for treatment of hypochlohydria and achlorhydria. These are two of the ingredients of this medical food product. 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. ODG guidelines do not address other ingredients of this product. There is still minimal scientific evidence and lack of adequate clinical trials to support the benefits of Choline and Glutamic acid in combination with other drugs. These products still have limited scientific evidence for efficacy and safety profile for the management of pain. The individual contents of these medical food products are not recommended by ODG. The medical necessity of Sentra AM #60 is not established at this time.