

Case Number:	CM15-0019544		
Date Assigned:	02/09/2015	Date of Injury:	10/05/2011
Decision Date:	03/25/2015	UR Denial Date:	01/05/2015
Priority:	Standard	Application Received:	02/02/2015

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:

The injured worker is a 53 year old female who sustained an industrial injury on 10/05/2011. On progress noted dated 12/20/2014 much on note is not legible. Diagnosis included herniated nucleus pulposus. She was noted to have a decreased range of motion of lumbar spine with positive spasms and positive Phanel and Tinel sign in bilateral hands. Treatment plan included medication, therapies of chiropractic and acupuncture, urinalysis and lumbar spine shockwave therapy. The patient sustained the injury when she jammed her finger in the sliding door. The medication list include theramine, Gabadone, Sentra AM. She has had a urine drug toxicology report on 10/29/14 and on 11/25/14 that was negative for opioid.

IMR ISSUES, DECISIONS AND RATIONALES

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

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 8th Edition (web), Pain (updated 03/18/15) Sentra PM Medical foods.

Decision rationale: Request: Sentra AM #60 It is claimed that Sentra AM provides the amino acids that are precursors to the neurotransmitters that control restorative sleep. Sentra AM is a medical food from [REDACTED] intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. Sentra PM is a patented blend of neurotransmitters and n 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 of Sentra PM, Sentra PM 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. 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. These are two of the ingredients of this medical food product. 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. 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; " There is no documented dietary deficiency in this patient. There is no documented evidence that the patient has hypoproteinemia or nutritional deficiencies or malnutrition. The medical necessity of the request for Sentra AM #60 is not fully established in this patient.