

Case Number:	CM14-0156573		
Date Assigned:	10/10/2014	Date of Injury:	07/13/2005
Decision Date:	11/10/2014	UR Denial Date:	08/29/2014
Priority:	Standard	Application Received:	09/24/2014

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 51 year old male patient who sustained a work related injury on 7/13/2005. The diagnoses include lumbar radiculopathy, post-laminectomy syndrome, lumbar region, failed back surgery syndrome, spasm of muscle, long-term (current) use of medications, encounter for therapeutic drug monitoring, non-steroidal anti-inflammatory drug (NSAID) induced gastritis, and opioid related constipation. Per the doctor's note dated 4/11/14, patient has complaints of chronic low back pain with numbness and tingling in his left leg and toes; numbness and tingling in the bilateral hands. Physical examination revealed walks with limp, favoring the left leg, bilateral tenderness and spasms of the L3-5 paraspinal muscles, decreased lumbar range of motion-Extension 5 degrees, flexion 40 degrees; bilateral lateral bending 5-10 degrees, numbness in the medial distribution of both hands, 5+ strength in right lower extremity and 4/5 in left lower extremity and decreased sensory to pin-prick along the left lateral leg and thigh. The medications list includes butran patch, prilosec, gabapentin, docuprene, flexeril and sprix. He has had lumbar MRI on 6/9/2009. His surgical history includes morphine pump implant on 10/13/10, discectomy on 8/30/2005, laminectomy on 12/8/2007, and spinal cord stimulation (SCS) unsuccessful trial on 3/18/2009. He has had urine drug screen on 2/4/14 which was inconsistent for morphine and buprenorphine; urine drug screen on 9/1/11 with negative results. He has had psychotherapy and injections for this injury.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (updated 10/06/14) 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 manufacturer's the Sentra, "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. 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. The medical necessity of 1 prescription Sentra AM #60 is not established at this time.

1 prescription Sentra PM #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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (updated 10/06/14) Medical food, Sentra PM

Decision rationale: It is claimed that Sentra PM provides the amino acids that are precursors to the neurotransmitters that control restorative sleep. Sentra PM 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 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 hypochlorhydria 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 Glutamate 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 1 prescription Sentra PM #60 is not established at this time.

1 prescription Theramine #90: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (updated 10/06/14) Medical food, Theramine

Decision rationale: Theramine is a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine). Per the cited guidelines theramine is "Not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline

supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended."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 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 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 1 prescription Theramine #90 is not established at this time.