

<b>Case Number:</b>	CM14-0199291		
<b>Date Assigned:</b>	12/09/2014	<b>Date of Injury:</b>	09/10/2012
<b>Decision Date:</b>	01/26/2015	<b>UR Denial Date:</b>	11/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/28/2014

### 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 Physical Medicine Rehabilitation, has a subspecialty in Interventional Spine 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:

The patient is a 46 year old male with an injury date on 09/10/2012. Based on the 10/23/2014 hand written Doctor's First report provided by the treating physician the patient complains of 7/10 abdominal pain, 4/10 left knee pain, and 6/10 low back pain. The 09/11/2014 report indicates the patient complains of bilateral knee pain that is a 7/10. "Pain feels very numb and radiates down to feet." The patient also complains of pain in the bilateral hand and lumbar spine with numbness. The patient states "medication helps and therapy helps reduce pain. IF unit and cold therapy helps as well." Physical exam reveals tenderness at the left knee and lumbar spine with decreased range of motion. The diagnoses are:1. Left knee meniscal tear2. L/S disc protrusion3. Ventral Hernia4. MyospasmThe treatment plan is to request for therapy, chiropractic care, UDS, medical foods, cream, and return in 4 weeks for a follow up evaluation. The patient work status is "remain off work. "There were no other significant findings noted on this report. The utilization review denied the request for (1) Gabadone #60, (2) Sentra AM #60, (3) Sentra PM #60, and (4) Theramine #90 on 11/11/2014 based on the Official Disability Guidelines (ODG). The requesting physician provided treatment reports from 11/22/2013 to 12/04/2014.

### 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:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines - TWC

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

**Decision rationale:** According to the 10/23/2014 report, this patient presents with 7/10 abdominal pain, 4/10 left knee pain, and 6/10 low back pain. The current request is for Gabadone #60. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG guidelines state "Not recommended. Gabadone is a medical food from [REDACTED] 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." The ODG guidelines do not support the use of Gabadone for chronic pain or for sleep aid. Therefore, the current request is not medically necessary.

**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 - TWC

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

**Decision rationale:** According to the 10/23/2014 report, this patient presents with 7/10 abdominal pain, 4/10 left knee pain, and 6/10 low back pain. The current request is for Sentra AM #60, a medical food. Sentra AM is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, and neurotoxicity-induced fatigue syndrome. Sentra AM is a patented blend of neurotransmitter and neurotransmitter precursors (choline bitartrate and glutamate); activators of precursor utilization (acetyl-L carnitine, glutamate, and cocoa powder). The MTUS and ACOEM guidelines are silent when it comes to this product. ODG on medical food states that for Choline, "There is no known medical need for choline supplementation." MTUS also states that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, choline, and ingredient in Sentra is not supported by ODG guidelines. Therefore, the current request is not medically necessary.

**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 - TWC

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

**Decision rationale:** According to the 10/23/2014 report, this patient presents with 7/10 abdominal pain, 4/10 left knee pain, and 6/10 low back pain. The current request is for Sentra PM #60. The ODG guidelines states that, "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." ODG further states that for each ingredient: for choline, "There is no known medical need for choline supplementation"; for 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"; for 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 this case, choline, and ingredient in Sentra PM is not supported by ODG guidelines. Therefore, the current request is not medically necessary.

**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 - TWC

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter: Theramine.

**Decision rationale:** According to the 10/23/2014 report, this patient presents with 7/10 abdominal pain, 4/10 left knee pain, and 6/10 low back pain. The current request is for Theramine #90 a medical food. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG guidelines state that Theramine is a proprietary medication of [REDACTED]. Its intended use is in the management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. ODG further states for each ingredient, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; for Choline, "There is no known medical need for choline supplementation"; L-Arginine, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, "There is no indication for the use of this product." It does not appear that there is any guideline to support this product in the management of chronic pain. Therefore, the current request is not medically necessary.