

Case Number:	CM15-0020495		
Date Assigned:	02/10/2015	Date of Injury:	03/19/2013
Decision Date:	04/01/2015	UR Denial Date:	01/06/2015
Priority:	Standard	Application Received:	02/03/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 56 year old female injured worker suffered and industrial injury on 3/19/2013. The diagnoses were bilateral hand pain, displacement lumbar intervertebral disc without myelopathy. The treatments were acupuncture, electromyography/nerve conduction velocity, right wrist MAGNETIC RESONANCE IMAGING. The treating provider reported low back pain radiating to the right hip with numbness and tingling in the right leg. On exam there was decreased sensation in the right leg, tenderness and decreased range of motion to the lumbar spine with positive straight leg raise as well as numbness in the hands, insomnia, anxiety and depression. The Utilization Review Determination on 1/6/2015 non-certified: 1. Gabadone #60, citing ODG. 2. Sentra AM #60, citing ODG. 3. Sentra PM #60, citing ODG. 4. Theramine #90, citing ODG.

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 ODG, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines chapter 'Pain (chronic)' and topic 'GABAdone'.

Decision rationale: The 56 year old patient presents with pain in the lumbar spine, rated at 8/10, that radiates to right leg, as per progress report dated 09/17/14. The request for GABADONE #60. The RFA for this request is dated 12/09/14, and the patient's date of injury is 03/19/13. The patient is also experiencing swelling, weakness, numbness and tingling in the right wrist/hand. Diagnoses included lumbar disc protrusion, lumbar facet syndrome, right wrist pain, myospasm and right sciatica. Sudoscan report, dated 12/12/14, revealed abnormal hands and feet symmetry. EMG report dated 12/10/14 reveals C6-7 cervical radiculopathy. The patient has been allowed to return to modified work, as per progress report dated 12/08/14. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG guidelines, chapter 'Pain (chronic)' and topic 'GABAdone', state "Not recommended. GABAdone" is a medical food from [REDACTED], [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. In this case, most progress reports are handwritten and not very legible. The patient suffers from lower back and right leg pain. The treater, however, does not document any sleep disturbances or anxiety secondary to pain for which GABAdone is generally used. Nonetheless, ODG guidelines do not recommend GABAdone to patients with pain and insomnia. Hence, the 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 ODG, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Website <http://tmedpharma.com/docs/Medical-Foods-by-issacson.pdf>.

Decision rationale: The 56 year old patient presents with pain in the lumbar spine, rated at 8/10, that radiates to right leg, as per progress report dated 09/17/14. The request for SENTRA AM #60. The RFA for this request is dated 12/09/14, and the patient's date of injury is 03/19/13. The patient is also experiencing swelling, weakness, numbness and tingling in the right wrist/hand. Diagnoses included lumbar disc protrusion, lumbar facet syndrome, right wrist pain, myospasm and right sciatica. Sudoscan report, dated 12/12/14, revealed abnormal hands and feet symmetry. EMG report dated 12/10/14 reveals C6-7 cervical radiculopathy. The patient has been allowed to return to modified work, as per progress report dated 12/08/14. MTUS, ACOEM, and ODG guidelines are silent of Sentra AM. As per a document published at <http://tmedpharma.com/docs/Medical-Foods-by-issacson.pdf>, Sentra AM is purely a cholinergic modulator, providing supplementation in choline and acetylcarnitine which are both acetylcholine precursors. Its claims include the ability to increase amounts of acetylcholine at the molecular level. Small double-blinded trials with emphasis on imaging data conducted by the manufacturer have demonstrated increased choline in the CNS of treated patients versus selected

subjects. The indication thus spans entities as variable as fibromyalgia, sleep/arousal dysregulation syndromes and cognitive decline. In this case, progress reports are handwritten and not very legible. The request for Sentra AM is noted in progress report 12/08/14. The treater, however, does not explain the purpose of this request. There is no discussion about the patient's sleep issues, fibromyalgia and cognitive decline. Hence, the 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 ODG, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain chapter, Sentra PM Pain chapter, Medical foods.

Decision rationale: The 56 year old patient presents with pain in the lumbar spine, rated at 8/10, that radiates to right leg, as per progress report dated 09/17/14. The request for SENTRA PM #60. The RFA for this request is dated 12/09/14, and the patient's date of injury is 03/19/13. The patient is also experiencing swelling, weakness, numbness and tingling in the right wrist/hand. Diagnoses included lumbar disc protrusion, lumbar facet syndrome, right wrist pain, myospasm and right sciatica. Sudoscan report, dated 12/12/14, revealed abnormal hands and feet symmetry. EMG report dated 12/10/14 reveals C6-7 cervical radiculopathy. The patient has been allowed to return to modified work, as per progress report dated 12/08/14. The ODG guidelines states that, "Sentra PM" is a medical food from [REDACTED], [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, progress reports are handwritten and not very legible. The request for Sentra PM is noted in progress report 12/08/14. The treater, however, does not explain the purpose of this request. There is no diagnosis of sleep disturbances or depression. Additionally, Sentra PM contains choline which is not recommended by ODG guidelines. Hence, the 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 ODG, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines chapter 'Pain (Chronic)' and

topic 'Medical Foods'Website

<http://www.nutrientpharmacology.com/PDFs/monographs/theramine-mono-graph.pdf>.

Decision rationale: The 56 year old patient presents with pain in the lumbar spine, rated at 8/10, that radiates to right leg, as per progress report dated 09/17/14. The request for THERAMINE # 90. The RFA for this request is dated 12/09/14, and the patient's date of injury is 03/19/13. The patient is also experiencing swelling, weakness, numbness and tingling in the right wrist/hand. Diagnoses included lumbar disc protrusion, lumbar facet syndrome, right wrist pain, myospasm and right sciatica. Sudoscan report, dated 12/12/14, revealed abnormal hands and feet symmetry. EMG report dated 12/10/14 reveals C6-7 cervical radiculopathy. The patient has been allowed to return to modified work, as per progress report dated 12/08/14. MTUS and ACOEM guidelines are silent on medical foods. However, ODG guidelines, chapter 'Pain (Chronic)' and topic 'Medical Foods', state that medical foods such as Theramine are not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. In this case, progress reports are handwritten and not very legible. The request for THERAMINE # 90 is noted in progress report 12/08/14. The treater, however, does not explain the purpose of this request. Theramine is a medical food containing 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), as per <http://www.nutrientpharmacology.com/PDFs/monographs/theramine-mono-graph.pdf>. While the ODG guidelines do not discuss every ingredient found in Theramine, they state that L-arginine is "not indicated in current references for pain or inflammation." Regarding L-serine, the guidelines state "There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." Regarding GABA, the guidelines state that "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." Additionally, the guidelines do not recommend medical foods for the treatment of chronic pain. Thus, Theramine IS NOT medically necessary.