

<b>Case Number:</b>	CM14-0028057		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	08/05/2013
<b>Decision Date:</b>	08/15/2014	<b>UR Denial Date:</b>	02/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/05/2014

### 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 and 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 48-year-old female with a date of injury of 08/05/2013. The listed diagnoses per [REDACTED] are: Lumbar disk protrusion; Lumbar radiculopathy; Idiopathic peripheral autonomic neuropathy; unspecified disorder of autonomic nervous system. According to an initial progress report dated 01/15/2014 by [REDACTED], the patient presents with constant neck pain that radiates to the left upper extremity. The patient also complains of low back pain that radiates to the left lower extremity and rates her pain as 7/10 on a pain scale. An MRI of the lumbar spine from 10/07/2013 revealed L4-L5 2-3 mm right intraforaminal broad-based protruding disk with annular tear contributing to mild foraminal stenosis. L5-S1 reveals 1 to 2 mm right posteriorly protruded disk. The request is for GABAdone #60, Sentra AM #60, Sentra PM #60, Theramine #90, Trepadone #120, and left L5-S1 epidural injection.

### 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, Pain (Chronic), Gabadone and Medical Food.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines under pain chapter:Theramine.

**Decision rationale:** The ODG states that for ingredient 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. The MTUS Chronic Pain Guidelines 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, an ingredient in Sentra PM is not supported by the ODG. As such, the request is not medically necessary and appropriate.

**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, Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines under pain chapter:Theramine.

**Decision rationale:** The treater is requesting Sentra AM #60. 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-Lcarnitine, glutamate, and cocoa powder). The ODG on medical food states that for Choline, "There is no known medical need for choline supplementation." The MTUS Chronic Pain Guidelines 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 an ingredient in Sentra is not supported by the ODG. As such, the request is not medically necessary and appropriate.

**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, Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines The MTUS has the following regarding topical creams(p111, chronic pain section):Topical Analgesics Page(s): 111. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines under pain chapter:Theramine.

**Decision rationale:** The patient presents with neck and low back pain. The treater is requesting Sentra PM #60. Sentra PM has the same ingredients as Gabadone. The ODG 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 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. 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. The MTUS Chronic Pain Guidelines 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, an ingredient in Sentra PM is not supported by the ODG. As such, the request is not medically necessary and appropriate.

**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, Pain (Chronic).

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

**Decision rationale:** The patient presents with neck and low back pain. The treater is requesting Theramine #90. The ODG has the following regarding Theramine, 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. Theramine is not supported by the ODG. As such, the request is not medically necessary and appropriate.

**Trepadone #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

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

**Decision rationale:** The patient presents with neck and low back pain. The treater is requesting Trepadone. ODG has the following under its pain section, Trepadone is a medical food from [REDACTED] that is a proprietary blend of L-arginine, L- glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. The MTUS Chronic Pain Guidelines 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, L-serine an ingredient in Trepadone is supported by the ODG. Furthermore, for 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. As such, the request is not medically necessary and appropriate.

**Left L5/S1 epidural injection:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injections (ESIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines The Medical Treatment Utilization Schedule has the following regarding ESI's, under its chronic pain section: Page 46,47 Page(s): 46, 47.

**Decision rationale:** The patient presents with neck and low back pain. The treater is requesting a left L5-S1 epidural steroid injection. The MTUS Guidelines has the following regarding ESI under chronic pain section page 46 and 47, "Recommended as an option for treatment of radicular pain defined as pain in dermatomal distribution with corroborative findings of radiculopathy." In this case, an MRI of the lumbar spine revealed L5-S1 1-2 mm right posteriorly protruded disk only. The patient reportedly has pain down the left leg. 1-2mm disc to the right side is on the opposite side of the patient's symptoms and 1-2 mm disc protrusion is not significant. Given the lack of clear diagnosis of radiculopathy, the request is not medically necessary and appropriate.