

<b>Case Number:</b>	CM14-0077580		
<b>Date Assigned:</b>	07/18/2014	<b>Date of Injury:</b>	11/01/2008
<b>Decision Date:</b>	10/02/2014	<b>UR Denial Date:</b>	05/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/27/2014

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Texas. 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 injured worker is a 46 year old female who was injured on 11/01/08 while walking in the hallway, slipped in some water on the floor and fell landing on her buttocks, sustaining low back pain. Electrodiagnostic studies on 11/13/09 revealed an abnormal Electromyography (EMG) of right active S1 radiculopathy, and a normal nerve conduction study. Magnetic resonance imaging (MRI) scan of the lumbar spine on 12/21/09 revealed straightening of the lumbar spine due to either positional or related to spasm, degenerative and facet joint disease, 9x10x14 mm central and right paracentral disc protrusions/extrusion superimposed on diffuse broad based disc bulging along with hypertrophic changes at the bilateral facet joints and ligamentum flavum. There was redundancy at L4-L5 level, causing moderate to severe central and lateral recess stenosis. There is a 4mm right posterolateral disc protrusion at L5-S1 level encroaching into the right neural foramen. Clinical diagnosis includes L4-L5 and L5-S1 disc herniation with right radiculopathy. Injured worker has tried nonsteroidal anti-inflammatory agents, tramadol, and physical therapy without significant relief. In 01/12 the injured worker started complaining of pain in her neck while performing repetitive activities at work. In 02/05/12 the injured worker reported persistent low back pain that radiates to right hip/buttocks, and down to her right leg much more than the left leg. Clinical note dated 01/27/14 indicated injured worker complains of constant midline and right paraspinous and right trapezius discomfort which was rated as 5/10 on the pain scale. She also indicated occasional radiation of the neck pain down to the right upper extremity up to the right thumb, with intermittent numbness and tingling in both hands. She is also unable to perform activity above the shoulder level on the right due to pain. With regards to her lumbar pain, she indicated the pain level as generally 7/10 on the pain scale. Physical examination revealed discomfort on palpation in the midline of the cervical spine; muscle strength is 5/5/ in both upper and lower extremities. Straight leg raise maneuver is positive at 40

degrees bilaterally in the supine position. Management plan was discussed that included lumbar epidural steroid injection and lumbar decompressive surgery. There is no further clinical documentation provided for review limiting the ability to establish the injured worker's current status and substantiate the medical necessity of the requested medication. The previous requests for Gabadone #60, Sentra AM #60, Sentra PM #60, and Theramine #90 were non-certified on 05/21/14.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **RETROSPECTIVE REQUEST FOR GABADONE #60 DOS 4/7/14: Upheld**

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

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

**Decision rationale:** As per Official Disability Guidelines, Gabadone is a medical food that is a proprietary blend of Choline bitartrate, Glutamic acid, 5-Hydroxytryptophan and gamma aminobutyric acid, and is not medically recommended. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in injured workers who are experiencing anxiety related to sleep disorders. 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. Gamma-aminobutyric acid (GABA) 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. Glutamic acid supplement is used for treatment of hypochlorhydria and achlorhydria. 5-hydroxytryptophan supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. There is no indication in the clinical documentation that the injured worker has been evaluated for the above conditions. As such, the request for Gabadone 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, Medical Food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), online version, Pain (Chronic), Sentra AM

**Decision rationale:** As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. Sentra AM is intended for use in management of sleep disorders associated with depression that is a

proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no indication in the documentation that the injured worker has been diagnosed with depression or insomnia. Additionally, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Sentra AM # 60 is not medically necessary. CAMTUS and ACOEM do not address this issue.

**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, Medical Food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), online version, Pain(Chronic), Sentra PM

**Decision rationale:** As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. Sentra PM is intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no indication in the documentation that the injured worker has been diagnosed with depression or insomnia. Additionally, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Sentra PM #60 is not medically necessary. CAMTUS and ACOEM do not address this issue.

**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, Medical Food.

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

**Decision rationale:** As noted in the Pain Chapter of the Official Disability Guidelines, Theramine is not recommended for use in chronic pain management. Theramine is a medical food that is a proprietary blend of gamma-amino butyric acid [GABA] and choline tartrate, 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. There are no high quality studies that support the use of Theramine. Additionally, the use of herbal medicines or medical foods is not recommended. Moreover, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Theramine #90 is not medically necessary.