

<b>Case Number:</b>	CM14-0115108		
<b>Date Assigned:</b>	08/04/2014	<b>Date of Injury:</b>	04/14/2013
<b>Decision Date:</b>	10/07/2014	<b>UR Denial Date:</b>	06/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/22/2014

### 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 Management 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 47 year old male who had a work-related injury on 04/14/13. He injured his back while he was working construction, and after working and bending while taking a roof down, he was working 15 hours straight he started noticing low back pain with radiation to bilateral lower extremities. The injured worker has been treated with Anaprox, Prilosec, Flexeril, Neurontin, Medipatch with Lidocaine, TENS unit, and home exercise program. MRI of the lumbar spine dated 06/06/13 left paramedian disc protrusion at L4-5 which is increased slightly in the extension position. The injured worker has also had epidural steroid injections and physical therapy. Most recent medical record submitted for review is dated 02/18/14 the injured worker has persistent low back pain and varies day to day. Today is a better day for him and it is rated 5/10. The medications (Ultram, Anaprox, and Neurontin) reduce pain by greater than 50% but still with low back pain with radiation to lower extremities, left more than right, and we are awaiting authorization for lumbar epidural steroid injection and for physical therapy after the injection. No physical examination on this date. Diagnoses include lumbar radiculopathy and muscle spasms. Current request is for Theramine tid #60, Sentra PM bid #60, Sentra AM bid #60. Prior utilization review dated 06/24/4 was non-certified.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine tid #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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (ODG) 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-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. There are no high quality studies that support the use of Theramine. Additionally, the use of herbal medicines or medical foods is not recommended. Additionally, there is no indication the patient has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Theramine cannot be recommended as medically necessary.

**Sentra PM bid #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

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

**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 patient has been diagnosed with depression or insomnia. Additionally, there is no indication the patient has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Sentra PM # 60 cannot be recommended as medically necessary.

**Sentra AM bid #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

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

**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 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 patient has been diagnosed with depression or insomnia. Additionally, there is no indication the patient has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Sentra AM # 60 cannot be recommended as medically necessary.