

<b>Case Number:</b>	CM14-0093963		
<b>Date Assigned:</b>	07/25/2014	<b>Date of Injury:</b>	06/01/2010
<b>Decision Date:</b>	09/03/2014	<b>UR Denial Date:</b>	05/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/20/2014

### 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 32-year-old male injured on 06/01/10 due to undisclosed mechanism of injury. Diagnoses included lumbar decompression and fusion. Clinical note dated 06/12/14 indicated the injured worker presented complaining of low back pain. The injured worker discontinued Naprelan, continued Prilosec and reported stomach pain improved. The injured worker continued to receive diazepam from his family doctor in addition to soma. Evaluating provider previously advised the injured worker to discontinue soma and initiate Robaxin. The injured worker underwent two previous epidural steroid injections with the second providing approximately 50% improvement in pain symptoms. Physical examination revealed spasms to the low back with 40 degrees of flexion and 10 degrees of extension, straight leg raise positive for back pain, and all muscle groups tested 5/5. Treatment plan included third and final epidural steroid injection, discontinuation of Edular, continuation of Prilosec 20mg twice a day, Colace 100mg three times a day, and Norco four times a day. The injured worker was also referred for detoxing of pain medications. Urine drug screen was inconsistent for prescribed medications. The initial request for GABAdone #60, Sentra AM #60, Sentra PM #60 and Theramine #90 was non-certified on 05/19/14.

### 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 (ODG), GABA done.

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

**Decision rationale:** As noted in the Official Disability Guidelines - Online version, Gabadone is a medical food that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan and Gabadone. 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. Additionally, the use of herbal medicines or medical foods is not recommended. Further, 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 Gabadone #60 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 (ODG), Sentra PM.

**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 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. 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.

**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 (ODG), Sentra PM.

**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 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. 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.

**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 (ODG).

**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), 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 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.