

<b>Case Number:</b>	CM15-0179846		
<b>Date Assigned:</b>	09/21/2015	<b>Date of Injury:</b>	01/12/2011
<b>Decision Date:</b>	11/18/2015	<b>UR Denial Date:</b>	08/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/14/2015

### 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: Tennessee, Florida, Ohio  
 Certification(s)/Specialty: Surgery, Surgical Critical Care

### 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 44 year old female, who sustained an industrial injury on 1-12-2011. The medical records indicate that the injured worker is undergoing treatment for cervical disc protrusion, cervical radiculopathy, thoracic spine sprain-strain, lumbar disc protrusion, lumbar radiculopathy, right shoulder sprain-strain, right rotator cuff syndrome, left shoulder myalgia-myositis, right chondromalacia patella, and status post right ankle surgery. According to the progress report dated 5-21-2015, the injured worker presented with complaints of constant neck pain (8 out of 10) with radiation into her bilateral upper extremities, associated with numbness and tingling, constant, mid and low back pain (9 out of 10) with radiation into the bilateral lower extremities, associated with numbness and tingling, constant right shoulder pain (10 out of 10), frequent left shoulder pain (7 out of 10), frequent right knee pain (7 out of 10), and occasional right foot pain (5 out of 10). The physical examination of the cervical spine reveals tenderness to palpation, tenderness and spasm along the upper trapezius bilaterally, and reduced range of motion. Examination of the lumbar spine reveals tenderness and palpable spasm over the paravertebral muscles and lumbar spine bilaterally, reduced range of motion, and positive straight leg raise on the right. The current medications are Norco, Cyclobenzaprine, Omeprazole, and Terocin patch. Previous diagnostic studies include MRI studies. Treatments to date include medication management, home exercise program, and surgical intervention. Per notes, the injured worker is able to resume her regular work duties. The original utilization review (8-17- 2015) had non-certified a request for Theramine, Sentra AM, Sentra PM, and Gabadone.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Theramine per 05/21/2015 order Qty 180: 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 chapter, medical foods; Theramine.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. According to the Official Disability Guidelines (ODG), Theramine is: Not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). This patient has chronic shoulder and back pain secondary to an industrial accident. Per ODG, theramine is specifically not indicated for the treatment of chronic pain. Therefore, based on the submitted medical documentation, the request for theramine is not medically necessary.

### **Sentra AM per 05/21/2015 order Qty 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 AM/PM.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The Official Disability Guidelines state that Sentra AM is not recommended. Sentra AM is a medical food from Targeted Medical Pharm, Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. There was no rationale submitted in the submitted documentation to indicate the use of Sentra AM other than the patient's chronic pain syndrome. There were no other significant factors provided to justify the use outside of the current guidelines. Given the evidence based guidelines and the lack of submitted documentation, the request would not be indicated. Therefore, based on the submitted medical documentation, the request for Sentra AM is not medically necessary.

### **Sentra PM per 05/21/2015 order Qty 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 AM/PM.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The Official Disability Guidelines state that Sentra PM is not recommended. Sentra PM is a medical food from Targeted Medical Pharm, Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. There was no rationale submitted in the submitted documentation to indicate the use of Sentra PM other than the patient's chronic pain syndrome. There were no other significant factors provided to justify the use outside of the current guidelines. Given the evidence based guidelines and the lack of submitted documentation, the request would not be indicated. Therefore, based on the submitted medical documentation, the request for Sentra PM is not medically necessary.

**Gabadone per 05/21/2015 order Qty 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, Medical foods.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. Gabadone is a medical food product which includes the following ingredients: 5-Hydroxytryptophan, choline bitartrate, gamma aminobutyric acid, cocoa extract, l-glutamic acid, whey protein, griffonia extract, valerian root, acetyl l-carnitine, ginkgo biloba, and grape seed extract, which are all generally recognized as safe. Gabadone is formulated for the treatment of sleep disorders. The MTUS is silent in regards to Gabadone. The ODG states that some individual medical foods may be recommended in special circumstances where there is a clear nutritional deficiency. However, Gabadone is not recommended by the ODG. None of these ingredients found in Gabadone, however, are considered first-line therapy for sleep disorders, mostly due to limited quality studies. Since the specific product, Gabadone, includes multiple ingredients that together have even less evidence of benefit and safety, it is unreasonable to suggest this as an approved product for recommendation. Therefore, based on the submitted medical documentation, the request for Gabadone is not medically necessary.