

<b>Case Number:</b>	CM15-0045722		
<b>Date Assigned:</b>	03/18/2015	<b>Date of Injury:</b>	09/12/2014
<b>Decision Date:</b>	04/23/2015	<b>UR Denial Date:</b>	02/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/10/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal Medicine

### 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 53 year old male who sustained an industrial injury on 09/12/2014. Diagnoses include sprain right ankle, contusion of right thigh and right lower leg, lumbar strain, chest wall contusion, fracture of fibula, and fracture of ribs. Previous treatments included medications, physical therapy, and cast boot. Diagnostic studies included an MRI of the right knee, electromyogram of the bilateral lower extremities, cardio-respiratory diagnostic testing, sudoscan, and urine toxicology screening. MRI of the right knee on 12/2/14 showed tear of the lateral meniscus, partial thickness tear of the anterior cruciate ligament, focal chondral defect in the intercondylar notch of the femur, and joint effusion. Report from the primary treating physician dated 02/13/2015 noted that the injured worker presented for follow up. The subjective complaints, physical examination, and diagnoses were illegible due to handwriting. The treatment plan included requests for an MRI of the right leg, prescribed and dispensed creams, Theramine, Gabadone, Sentra AM, acupuncture and chiropractic therapy, urinalysis, sleep study, and return appointment in 4 weeks. On 2/24 15, Utilization Review (UR) non-certified requests for theramine #90, sentra AM #90, gabadone #60, and sentra PM # 60, citing the ODG.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**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.

**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 food, insomnia treatment, sentra pm.

**Decision rationale:** Sentra PM is a medical food 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. The MTUS does not address the use of hypnotics other than benzodiazepines. The ODG states that medical food is not recommended for the treatment of chronic pain. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. No evaluation of the potential causes of sleep disturbance was documented. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Sentra PM is not recommended. As such, the request for Sentra PM is not medically necessary.

**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.

**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 food, insomnia treatment, gabadone.

**Decision rationale:** Gabadone is a medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. No evaluation of the potential causes of sleep disturbance was documented. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Gabadone is not recommended for sleep disorders based on limited available research. As such, the request for gabadone is not medically necessary.

**Sentra AM #80:** 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.

**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 food.

**Decision rationale:** Sentra AM is a medical food intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory. The ODG states that medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The specific reason for prescription of sentra AM was not discussed. Due to lack of indication and lack of recommendation by the guidelines, the request for sentra AM 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, Pain.

**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 food, theramine.

**Decision rationale:** Theramine is medical food intended for use in the management of chronic pain syndromes. Theramine 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%). Per the ODG, theramine is not recommended for the treatment of chronic pain. The specific reason for prescription of theramine was not discussed. Due to lack of indication and lack of recommendation by the guidelines, the request for theramine is not medically necessary.