

<b>Case Number:</b>	CM15-0111426		
<b>Date Assigned:</b>	06/17/2015	<b>Date of Injury:</b>	02/25/2011
<b>Decision Date:</b>	08/17/2015	<b>UR Denial Date:</b>	06/04/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/09/2015

### 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: New York  
 Certification(s)/Specialty: Anesthesiology

### 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 43 year old female, who sustained an industrial injury on 02/25/2011. She reported injuring her left arm, shoulder, head, face, back, and hips after a fall at work. The injured worker is currently able to work with restrictions. The injured worker is currently diagnosed as having lumbar sprain/strain and lumbar radiculopathy. Treatment and diagnostics to date has included home exercise program, physical therapy, acupuncture, home Transcutaneous Electrical Nerve Stimulation Unit, and medications. In a progress note dated 12/04/2014, the injured worker presented with complaints of low back pain and left leg pain. Objective findings include decreased lumbar range of motion. The treating physician reported requesting authorization for Metformin, Sentra AM, Sentra PM, and Theramine.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Metformin:** 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), Pain chapter - Diabetes chapter.

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

**Decision rationale:** Metformin (Glucophage) is recommended as a first-line treatment of type 2 diabetes to decrease insulin resistance. Metformin is effective in decreasing both fasting and postprandial glucose concentrations. Metformin often has beneficial effects on components of the metabolic syndrome, including mild to moderate weight loss, improvement of the lipid profile, and improved fibrinolysis. Metformin is also effective as monotherapy and in combination with other antidiabetic agents, including sulfonylureas, TZDs, AGIs, DPP-4 inhibitors, GLP-1 agonists, and pramlintide. It can also be used in combination with insulin. Because of its relatively short duration of action, it is usually administered 2 to 3 times daily and is best tolerated if taken with meals. A long-acting, once-daily formulation is also available. Overall, most of the diabetes medications used alone decreased HbA1c by about 1 percentage point. Similar results were obtained with various two-drug combinations. Metformin performed better than several other classes by not increasing body weight and by lowering LDL-cholesterol. There was also a better safety profile with metformin in terms of risk for low blood sugar. In this case, there is no documentation that the patient has a diagnosis of type-2 diabetes. Medical necessity for the requested item has not been established. The requested item 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), Pain chapter - Diabetes chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Sentra Product information.

**Decision rationale:** Sentra AM is a Medical Food that is 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. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The requested medical food 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), Pain chapter - Diabetes chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Sentra Product information.

**Decision rationale:** Sentra PM is a Medical food that is intended for use in the management of sleep disorders associated with depression. It is a proprietary blend of choline bitartate, glutamate, and 5-hydroxytryptophan. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The requested medical food 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), Pain chapter - Diabetes chapter.

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

**Decision rationale:** According to the ODG, Theramine is an FDA regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Its mechanism of action is the production of neurotransmitters that help manage and improve the sensory response to pain and inflammation. This medication 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. There is no medical literature that supports the use of this medication for the treatment of chronic pain. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.