

<b>Case Number:</b>	CM14-0119455		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	09/06/2006
<b>Decision Date:</b>	10/02/2014	<b>UR Denial Date:</b>	07/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/28/2014

### 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 Family Medicine and is licensed to practice in California. 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:

This is a 58-year-old female who reported an industrial injury on 9/6/2006, over eight (8) years ago, attributed to the performance of her usual and customary job tasks. The patient complained of left wrist pain radiating down to the first, second, and third digits. The objective findings on examination included tenderness to palpation over the dorsal aspect of the hand and wrist; restricted range of motion. The treatment plan included the prescription of medical foods including Theramine #60; tramadol #90; and Sentra PM #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine #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, Medical Foods; Theramine

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods; Theramine

**Decision rationale:** There is no objective evidence provided by the provider to support the medial necessity of the prescribed medial food for the patient as opposed to conventional

medications. The cited diagnoses not support the medical necessity of the prescribed medical food. There is no objective evidence provided by the provider to override the recommendations of the CA MTUS for the prescription of medical foods as opposed to conventional oral pharmaceuticals. The patient has not been demonstrated to have failed treatment on conventional medications and the dispensed medical foods are not demonstrated to be medically necessary for the treatment of the effects of the industrial injury. The Theramine was prescribed to reduce pain and inflammation. Medical foods are not FDA approved. The use of Theramine is not supported by the national medical community and is not supported with double blind peer reviewed studies that demonstrate functional improvement. The prescription of medical food is reportedly directed to nutritional deficiencies associated with chronic pain; however, there is no objective evidence that this patient has nutritional deficiencies that reportedly occur by the diversion of essential amino acids. The medical necessity of the prescribed medical food Theramine for pain relief and anti-inflammation for the cited diagnoses was not supported with any evidence-based guidelines. The rationale for the prescription of medical foods over prescribed oral medications is not explained fully or supported with objective evidence. The prescription of the medical foods has not been supported with the criteria recommended by the Official Disability Guidelines. There is no demonstrated medical necessity for the prescribed Theramine. The use of the prescribed medical foods is based on anecdotal evidence and there is no evidence based medicine or current literature to establish the effectiveness medical foods or to establish functional capacity improvement with the use of the medical foods. There is no medical necessity for the prescription of this medical food for chronic hand/wrist pain. There is no subjective/objective evidence provided to support the use of Theramine over a generic oral prescription for the same component medications. There is no documented objective evidence that the patient requires both the oral medications and the compounded medication for the treatment of the stated diagnoses. The objective findings in the clinical documentation provided does not support the prescription of Theramine as the compounded medications were not subjectively or objectively documented to have improved function or decreased pain. Theramine is a Medical Food product advertised to aid in the nutritional management of pain syndromes. Theramine is purported to stimulate the production of serotonin, GABA, norepinephrine, nitric oxide and acetylcholine, the neurotransmitters that are reported to be involved or deficient in pain disorders. If the timing and secretion of these neurotransmitters are effectively modulated, it is alleged that acute and chronic pain disorders are more effectively managed. Theramine is advertised to provide L-Arginine at low dose along with choline and L-glutamine to inhibit the NMDA and opioid receptors. Theramine is reported to be prescribed to manage the nutritional deficiencies associated with pain syndromes. There is no objective evidence to support the medical necessity of the medical food Theramine #60 for the treatment of the provided diagnosis.

**Trepadone #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) Medical Food; Trepadone

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods; Theramine

**Decision rationale:** The patient was prescribed Trepadone, a medical food or dietary supplement to treat inflammation and arthritis. Trepadone is a dietary supplement that is reported to modulate inflammation through the use of fish oil fatty acids. There is no rationale supported with objective evidence by the treating physician to demonstrate the medical necessity for this

dietary supplement. Dietary supplements are not considered medically necessary for the treatment of injured workers. There are no CA MTUS recommendations for the use of dietary supplements for the treatment of industrial injuries. There is no rationale supported with objective evidence to support the medical necessity of the prescribed Trepadone #90.

**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 Sentra PM

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

**Decision rationale:** The prescription of the medical food Sentra PM (Strazepam) as a medical food is not recommended by the ACOEM Guidelines or the Official Disability Guidelines for the treatment of insomnia or a sleep disorder. The prescribed Sentra PM was not demonstrated to be medically necessary. It is not clear that the patient is diagnosed with a sleep disorder or experiences occasional insomnia. There is no medical necessity for the prescription of Sentra PM for the patient. There is no documented evidence that the patient has failed the use of the numerous available sleep aids over-the-counter. The request for the authorization of Sentra PM is not supported with objective medically based evidence. There is no medical necessity for the medical food Sentra PM for the effects of the industrial injury. There is no evidence that this prescribed medical food provides functional improvement or even helps with sleep. The prescription of medical foods is not recommended by the CA MTUS or the Official Disability Guidelines. The use of the medical food is not supported with clinical evidence or supported with objective peer-reviewed evidence. The medical foods prescribed in addition to the oral medications prescribed are not demonstrated to be medically necessary. Sentra PM was prescribed for sleep. The medical food is prescribed routinely for sleep and not on a prn basis. The medical food is not FDA approved. There is no documented failure of the many sleep remedies available OTC. There is no demonstrated medical necessity for the continuation of a sleep aid eight (8) years after the DOI. There is no medical necessity for a medical food for increased energy with AM or PM formulations. Therefore, the request is not medically necessary.