

Case Number:	CM14-0105442		
Date Assigned:	09/12/2014	Date of Injury:	03/13/2013
Decision Date:	10/07/2014	UR Denial Date:	06/18/2014
Priority:	Standard	Application Received:	07/07/2014

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 female patient who reported an industrial injury 3/13/2013, over 18 months ago, attributed to her usual and customary job tasks. The patient was noted be treated for neck and low back pain. The diagnoses included cervicgia, lumbago, and bilateral shoulder sprain/strain. The treatment plan included physical therapy; topical compounded analgesics; and prescribed medical foods that included Theramine #90 and Percura #120.

IMR ISSUES, DECISIONS AND RATIONALES

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

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: 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 convention 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 medial 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 neck and back 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 advertized 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.

Percura #120: 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: 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: [REDACTED] announced preliminary data indicating its new product, Percura capsules, reduced symptoms of pain and numbness related to peripheral neuropathy. Percura is a new amino-acid based prescription medical food designed for the dietary management of the metabolic processes associated with pain, inflammation, and loss of sensation due to peripheral neuropathy. Preliminary studies demonstrated Percura reduced numbness in 57% of patients and pain in 56% of patients after 30 days of treatment. The 60-day study will be completed by the end of 2012. Percura is a prescription medical food that acts by providing the nutritional requirements that support the synthesis and physiological activities of neurotransmitters involved in neuropathic pain. Percura is a medical food and is a combination of amino acids. The medical necessity of the prescribed medical food Percura 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 Percura. 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 neck and back pain. There is no subjective/objective evidence provided to support the use of Percura 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 Percura as the compounded medications were not subjectively or objectively documented to have improved function or decreased pain. There is no objective evidence or rationale by the requesting provider to support the medical necessity of the medical food Percura #60 for the treatment of the provided diagnosis.

