

Case Number:	CM15-0140653		
Date Assigned:	07/30/2015	Date of Injury:	11/28/2000
Decision Date:	09/02/2015	UR Denial Date:	06/24/2015
Priority:	Standard	Application Received:	07/20/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 55 year old female, who sustained an industrial injury on 11-28-2000. The medical records submitted for this review did not include the details regarding the initial injury or prior treatments to date. Diagnoses include thoracic sprain, strain; right shoulder partial rotator cuff tear; left shoulder tendinitis, and bilateral carpal tunnel syndrome. Currently, she complained of pain in the neck, mid back, bilateral shoulders and bilateral wrists. On 2-17-15, the physical examination documented decreased cervical spine range of motion with tenderness and muscle spasms. The wrists were noted to be tender with positive Phalen's tests bilaterally. The plan of care included prescriptions. The appeal requested authorization for Theramine #90; Sentra PM #60; and Trepadone #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine quantity 90.00: 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: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter, under Medical Foods and Other Medical Treatment Guidelines www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf.

Decision rationale: This patient presents with neck, mid back, bilateral shoulders and bilateral wrists pain. The current request is for Theramine quantity 90.00. The RFA is dated 06/17/15. Treatment history included physical therapy, medications, and HEP. The patient is not working. MTUS and ACOEM guidelines are silent regarding Theramine. ODG guidelines, Pain (Chronic) Chapter, under Medical Foods, state that medical foods such as Theramine are "Not recommended for chronic pain. 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". According to progress report 05/29/15, the patient presents with neck pain radiating to the upper extremities, constant low back pain and occasional bilateral shoulder and wrist pain. Examination revealed decreased range of motion due to pain in the cervical spine, right shoulder and right wrist. The treater requested Theramine "for pain". Theramine was initiated on 08/05/14. Per www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf. Theramine is a medical food containing a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine). While the ODG guidelines do not discuss every ingredient found in Theramine, ODG does state that L-arginine is "not indicated in current references for pain or 'inflammation". Regarding L-serine, the guidelines state "There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement". Regarding GABA, the guidelines state that "This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety". Additionally, ODG guidelines do not recommend medical foods for the treatment of chronic pain. The treater has not provided a medical rationale to prescribe a medical food that contains ingredients not supported by the ODG. Therefore, the request is not medically necessary.

Sentra PM quantity 60.00: 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: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter under Medical Foods Pain Chapter under Sentra PM.

Decision rationale: This patient presents with neck, mid back, bilateral shoulders and bilateral wrists pain. The current request is for Sentra PM Quantity 60.00. The RFA is dated 06/17/15. Treatment history included physical therapy, medications, and HEP. The patient is not working.

ODG Guidelines, Pain Chapter under Medical Foods states: "Medical food: Intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must meet the following criteria: (1) The product must be a food for oral or tube feeding, (2) The product must be labeled for dietary management of a specific medical disorder, (3) The product must be used under medical supervision...Not recommended for chronic pain". ODG Guidelines, Pain Chapter under Sentra PM States: "Sentra PM is a medical food from Targeted Medical Pharma Inc., Los Angeles, California, intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan". ODG further states that for choline, "there is no known medical need for choline supplementation". For glutamic acid, "this supplement is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer, and critical illnesses. It is generally used for digestive disorders and complementary medicine". For 5-hydroxytryptophan, "the supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has been found to be effective for depression". According to progress report 05/29/15, the patient presents with neck pain radiating to the upper extremities, constant low back pain and occasional bilateral shoulder and wrist pain. Examination revealed decreased range of motion due to pain in the cervical spine, right shoulder and right wrist. The treater requested Sentra PM "1-2 tabs at bed time for sleep disorders associated with depression". It is not clear when Sentra PM was initiated. It appears to be an initial request. In this case, the treating physician has dispensed Sentra PM which consists of choline bitartrate, glutamate, and 5-hydroxytryptophan. Both choline and glutamic acid are not supported by ODG Guidelines. The treater has not provided a medical rationale to prescribe a medical food that contains ingredients not supported by ODG. Therefore, the request is not medically necessary.

Trepadone quantity 90.00: 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: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) chapter, under Trepadone.

Decision rationale: This patient presents with neck, mid back, bilateral shoulders and bilateral wrists pain. The current request is for Trepadone quantity 90.00. The RFA is dated 06/17/15. Treatment history included physical therapy, medications, and HEP. The patient is not working. ODG guidelines, Pain (chronic) chapter, under Trepadone, states that the medical food is "Not recommended. Trepadone" is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa". The guidelines also state that "There is insufficient evidence to support use for osteoarthritis or for neuropathic pain". According to progress report 05/29/15, the patient presents with neck pain radiating to the upper extremities,

constant low back pain and occasional bilateral shoulder and wrist pain. Examination revealed decreased range of motion due to pain in the cervical spine, right shoulder and right wrist. The treater requested Trepadone "for pain and inflammation associated with joint disorders". It is not clear when Trepadone was initiated. It appears to be an initial request. ODG guidelines states that Trepadone is "not recommended" and ODG further states there is little support for its use for arthritis or for neuropathic pain. Hence, the request is not medically necessary.