

Case Number:	CM15-0183423		
Date Assigned:	09/24/2015	Date of Injury:	07/14/2011
Decision Date:	10/29/2015	UR Denial Date:	08/21/2015
Priority:	Standard	Application Received:	09/17/2015

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 63 year old male who sustained an industrial injury on 7-14-11. A review of the medical records indicates he is undergoing treatment for hiatal hernia, gastritis, constipation and diarrhea - suspect irritable bowel syndrome, weight gain, hypertension with left ventricular hypertrophy and diastolic function, sleep disorder - suspect obstructive sleep apnea, and diabetes mellitus. "Deferred" diagnoses include diffuse liver disease, glaucoma, post-traumatic headache, tinnitus, vertigo, psychiatric diagnosis, and orthopedic diagnosis. Medical records (6-30-15) indicate "improved constipation", as well as "unchanged" blood pressure, sleep quality, chest pain, and shortness of breath. The physical exam reveals clear lungs to auscultation, regular rate and rhythm of his heart, and a soft abdomen with "normoactive" bowel sounds. The injured worker denies complaints of acid reflux. The treating provider indicates "range of motion is deferred to the appropriate specialist". Diagnostic studies include a sleep study. A diabetes mellitus profile and urinalysis were ordered on the documented visit, as well as a body composition study and cardio-respiratory testing. His medications include Hydrochlorothiazide 25mg daily, Prilosec 20mg daily, Lidoderm 5% patches every 12 hours, Theramine, and Sentra PM. A low fat, low acid diet is recommended. A referral to a gastroenterologist and ophthalmologist is pending. The utilization review (8-21-15) indicates a request for authorization for Theramine #60 6 bottles, Sentra PM #60 3 bottles, and Lidoderm 5% patches with 2 refills. The requested treatments were denied with the following rationale: 1. Theramine - "guidelines state that Theramine is not recommended for the treatment of chronic pain" and "no indication that patient has dietary deficiency requiring supplementation with a medical food". 2. Sentra PM - "the request is not reasonable as there is no indication that there is a nutritional deficiency that could be addressed with medical food". 3. Lidoderm 5% patches - "primarily recommended for

neuropathic pain when trials of antidepressants and anticonvulsants have failed. The request is not reasonable as there is no documentation that there has been failure of first line therapy".

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #60 6 bottles: 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 food.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Medications for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medical Food, pages 758-760.

Decision rationale: Guidelines clearly states food supplements such as Theramine is not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. Additionally, Theramine is classified as medical food containing products that are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The provider has not documented any nutritional deficiency or medical conditions that would require nutritional supplementation as it relates to this patient's musculoskeletal injuries. The Theramine #60 6 bottles is not medically necessary and appropriate.

Sentra PM #60 3 bottles: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medical Food, pages 758-760.

Decision rationale: Sentra is a medical food supplement in alternative medicine. MTUS is silent on its use; however, ODG states to be considered, the product must, at a minimum, 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, disease, or condition for which there are distinctive nutritional requirements; (3) The product must be used under medical supervision. Based on a review of the available medical reports, there is no evidence to suggest that this patient has any type of condition to warrant the investigational use of this supplement. Sentra is not medically necessary and appropriate. The provider has not provided any documentation of medical necessity consistent with evidence-based, peer-reviewed, nationally recognized treatment guideline for Sentra or any other alternative supplements nor has submitted reports identified any nutritional deficiency or medical conditions that would require nutritional supplementation as it relates to this patient's injuries. Absent medical necessity, certification cannot be granted. The request for Sentra PM #60 3 bottles is not medically necessary and appropriate.

Lidoderm 5% patches with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch).

Decision rationale: Chronic symptoms and clinical findings remain unchanged with medication refilled. The patient exhibits diffuse tenderness and pain on the exam. The chance of any type of topical improving generalized symptoms and functionality significantly with such diffuse pain is very unlikely. Topical Lidocaine is indicated for post-herpetic neuralgia, according to the manufacturer. There is no evidence in any of the medical records that this patient has a neuropathic source for the diffuse pain. Without documentation of clear localized, peripheral pain to support treatment with Lidocaine along with functional benefit from treatment already rendered, medical necessity has not been established. There is no documentation of intolerance to oral medication as the patient is also on other oral analgesics. The Lidoderm 5% patches with 2 refills is not medically necessary and appropriate.