

Case Number:	CM14-0067253		
Date Assigned:	07/11/2014	Date of Injury:	02/07/2013
Decision Date:	04/13/2015	UR Denial Date:	05/06/2014
Priority:	Standard	Application Received:	05/12/2014

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. 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 53 year old male, who sustained an industrial injury on 2/7/2013. The diagnoses have included right knee internal derangement of the knee, right knee medial meniscus tear and right rotator cuff tear. Treatment to date has included knee arthroscopy (2013), physical therapy and medication. According to the progress report dated 4/9/2014, the injured worker complained of persistent shoulder and knee pain. Pain was rated 5/10 without medications and 4/10 with medications. The injured worker complained of weakness and inability to pivot on right knee. He was unable to squat or kneel. Physical exam revealed full range of motion right knee but positive pivot sign. Gait revealed a limp with right leg. Theramine, Sentra AM and Sentra PM were prescribed. On 5/6/2014, Utilization Review (UR) non-certified a request for Sentra AM 60 count, Sentra PM 60 count and Theramine 90 count. The Official Disability Guidelines (ODG) was cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM 60 count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter (Official Disability Guidelines).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain Chapter online (updated 4/16/15) for Medical Foods.

Decision rationale: The patient presents with weakness and inability to pivot on right knee. The request is for SENTRA AM 60 COUNT. The RFA provided is dated 04/16/14. Patient's diagnosis included right knee internal derangement of the knee, right knee medial meniscus tear and right rotator cuff tear. Treatments to date has included knee arthroscopy (2013), physical therapy, and medication. Patient is to return to modified duty. Sentra AM is a medical food. ODG-TWC guideline, Pain Chapter online (updated 4/16/15) for Medical Foods, states: Not recommended for chronic pain. The initiation date for this prescription is not known. Sentra AM is being prescribed for alertness and energy; however, there is no discussion about the patient's sleep issues, fibromyalgia, and cognitive decline. ODG-TWC guidelines do not recommend medical foods for chronic pain. Therefore, the request IS NOT medically necessary.

Sentra PM 60 count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter (Official Disability Guidelines).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain Chapter online (updated 4/16/15) for Medical Foods.

Decision rationale: The patient presents with weakness and inability to pivot on right knee. The request is for SENTRA PM 60 COUNT. The RFA provided is dated 04/16/14. Patient's diagnosis included right knee internal derangement of the knee, right knee medial meniscus tear and right rotator cuff tear. Treatments to date has included knee arthroscopy (2013), physical therapy, and medication. Patient is to return to modified duty. The ODG guidelines states that, "Sentra PM is a medical food from [REDACTED] intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan." ODG-TWC guideline, Pain Chapter online (updated 4/16/15) for Medical Foods, states: Not recommended for chronic pain. The initiation date for this prescription is not known. Sentra PM is being prescribed for sleep and energy; however, there is no indication of sleep disturbances or depression. Additionally, Sentra PM contains choline which is not recommended by ODG guidelines. Therefore, the request IS NOT medically necessary.

Theramine 90 count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter (Official Disability Guidelines).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines chapter 'Pain (Chronic)' and topic 'Medical Foods'Website
<http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>.

Decision rationale: The patient presents with weakness and inability to pivot on right knee. The request is for THERAMINE 90 COUNT. The RFA provided is dated 04/16/14. Patient's diagnosis included right knee internal derangement of the knee, right knee medial meniscus tear and right rotator cuff tear. Treatments to date has included knee arthroscopy (2013), physical therapy, and medication. Patient is to return to modified duty. MTUS and ACOEM guidelines are silent on medical foods. However, ODG guidelines, chapter 'Pain (Chronic)' and topic '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."The initiation date for this prescription is not known. Theramine is being prescribed to help absorption of NSAID. 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), as per <http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>. While the ODG guidelines do not discuss every ingredient found in Theramine, they 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, the guidelines do not recommend medical foods for the treatment of chronic pain. Thus, Theramine IS NOT medically necessary.