

Case Number:	CM15-0214590		
Date Assigned:	11/04/2015	Date of Injury:	08/04/2010
Decision Date:	12/29/2015	UR Denial Date:	10/07/2015
Priority:	Standard	Application Received:	11/02/2015

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 36 year old male who sustained an industrial injury on 8-4-10. A review of the medical records dated 9-14-15 did not indicate the injured workers diagnosis. Provider documentation dated 9-14-15 noted the work status as return to full duty "as a supervisor". Treatment has included right knee radiographic studies (9-14-15), transcutaneous electrical nerve stimulation unit and bracing. Objective findings dated 9-14-15 were not completed by the physician. The treating physician indicates that the urine drug testing result (date) showed no aberration. The original utilization review (10-7-15) denied a request for FMCC cream and Theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

FMCC cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The patient presents with right knee pain. The request is for FMCC CREAM. The request for authorization form is not provided. X-ray of the right knee, 09/14/15, is unremarkable. Physical examination of the knee reveals arthroscopic scars on the right knee. Range of motion of the knees is normal and symmetrical. There is no pain with mobility of the knees. There are some noises with flexion of the right knee. There is no tenderness along the joint lines of either knee. There is a slight positive patellofemoral inhibition sign on the right. Per progress report dated 09/14/15, the patient is returned to full duty. MTUS has the following regarding topical creams, Chronic Pain Section, p 111: "Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Treater does not specifically discuss this medication. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. The requested FMCC Cream contains Flurbiprofen, Menthol, Camphor, and Capsaicin. In this case, the treater does not document or discuss this patient presenting with arthritis/tendinitis for which the Flurbiprofen component of this topical medication would be indicated. Therefore, the request IS NOT medically necessary.

Theramine: 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) Pain (Chronic) Chapter, under Medical food.

Decision rationale: The patient presents with right knee pain. The request is for THERAMINE. The request for authorization form is not provided. X-ray of the right knee, 09/14/15, is unremarkable. Physical examination of the knee reveals arthroscopic scars on the right knee. Range of motion of the knees is normal and symmetrical. There is no pain with mobility of the knees. There are some noises with flexion of the right knee. There is no tenderness along the joint lines of either knee. There is a slight positive patellofemoral inhibition sign on the right. Per progress report dated 09/14/15, the patient is returned to full duty. MTUS and ACOEM guidelines are silent on medical foods. However, ODG Guidelines, Pain (Chronic) Chapter, under Medical food Section states, "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." Treater does not specifically discuss this medication. 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 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." Furthermore, the guidelines do not recommend medical foods for the treatment of chronic pain. In this case, 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.