MAXIMUS Federal Services

Case Number:	CM15-0053537		
Date Assigned:	03/27/2015	Date of Injury:	07/25/2007
Decision Date:	05/01/2015	UR Denial Date:	03/01/2015
Priority:	Standard	Application Received:	03/20/2015

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: New Jersey, New York
Certification(s)/Specialty: Family Practice

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 56 year old male who sustained an industrial injury on 07/25/2007. Diagnoses include left ankle and left knee sprain, history of fall due to instability of the left knee and compensatory right knee sprain. Treatment to date has included medications, and home exercise program. A physician progress note dated 02/13/2015 documents the injured worker complains of left ankle and left knee swelling and pain and due to the way he is walking his right knee is also bothering him now and he now has swelling in the right knee as well. He has an antalgic gait, and uses a straight cane to ambulate and he is unstable. He uses a wheel chair for longer distances. He has pain on palpation on the medial joint line of both knees and both are positive for swelling. Treatment requested is for Theramine 62.5/100mg #90, dispensed on 1/19/15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine 62.5/100mg #90, dispensed on 1/19/15: 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 Chapter, Theramine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines <Honey & Cinnamon> Page(s): 51. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical FoodFDA section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

Decision rationale: Theramine is a medical food used in the treatment of pain syndromes. Its ingredients include 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). The FDA defines medical food in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." 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. Theramine does not meet the requirement for medical food as stated by the FDA. There is no documented nutritional deficiency for which a medical food is required. One specific ingredient, cinnamon, is not recommended for chronic pain. When one component of a treatment is not recommended, then the whole treatment is not recommended. Therefore, Theramine is not medically necessary.