

Case Number:	CM15-0068132		
Date Assigned:	04/15/2015	Date of Injury:	04/09/2009
Decision Date:	05/19/2015	UR Denial Date:	03/17/2015
Priority:	Standard	Application Received:	04/10/2015

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: Colorado

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 55-year-old female, who sustained an industrial injury on 4/09/2009, with ongoing cumulative trauma noted as well. She reported headaches and was initially diagnosed with tension headaches. The injured worker was diagnosed as having abdominal pain, acid reflux secondary to non-steroidal anti-inflammatory medications, constipation, sleep disorder, dysphagia. Orthopedic diagnoses included neck pain, bilateral upper extremity radiculopathy, bilateral carpal tunnel syndrome, bilateral shoulder rotator cuff syndrome, and unspecified internal derangement of the right knee. Treatment to date has included diagnostics, medications, chiropractic, and physical therapy. Currently, the injured worker complains of unchanged dysphagia, abdominal pain, depression, anxiety, constipation, and sleep quality. Medications include Gabadone, Colace, Sentra AM, and Trepadone. Medication refills were requested. An Agreed Medical Evaluation, dated 11/06/2014, noted complaints regarding multiple areas, noting headaches, cervical pain, right knee pain, and low back pain. She was currently not working. Medication refills were requested.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trapadone #90 x 3 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, Medical Food.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 50. Decision based on Non-MTUS Citation FDA Orphan Drug Act and Amendments, FDA Nutrition Labeling and Education Act.

Decision rationale: California MTUS Guidelines do not address Trepadone specifically, so review of FDA acts, and available literature in Medline was conducted for evidence-based information. Review of available literature did not reveal any peer-reviewed, evidence-based studies that address Trepadone. Per vendor site, Trepadone is a "proprietary blend of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine) and neurotransmitters (gammaaminobutyric acid [GABA]); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory compounds (omega-3 fatty acids and histidine); immunomodulatory peptides (whey protein hydrolysate); precursors of functional components of joint connective tissue (glucosamine and chondroitin sulfate); and an adenosine antagonist (cocoa powder)," intended to treat joint conditions associated with pain and inflammation. The MTUS Guidelines do address the glucosamine / chondroitin component of the Trepadone: Per the Guidelines, the quality studies available for chondroitin show no improvement in pain with chondroitin use but no particular harm related to its use either. Though controversy still exists about interpretation of study results for glucosamine sulfate, the Guidelines note that some compelling evidence does exist to support glucosamine sulfate use in osteoarthritis of the knee, to possibly even slow progression of same. (Said compelling evidence cannot be extrapolated to other glucosamine salts, or to glucosamine included in food supplements.) As Trepadone is considered to be a medical food, Trepadone would also be indicated for specific nutrient deficiency, if the deficiency were documented, though no evidence-based articles support its efficacy for nutrient replacement. In Amendment to the FDA Orphan Drug Act, medical food is defined as "a food which is formulated to be consumed or administered orally or by tube feedings, 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." (21 U.S.C. 360ee (b) (3)) The FDA Nutrition Labeling and Education Act included the medical foods definition and established criteria for use: 1) Medical foods must be processed products, not used in naturally occurring state. 2) Medical foods are intended for "dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone" 3) Medical foods provide nutritional support specifically for the need a patient has based on medical evaluation 4) Medical foods are only to be used under medical supervision. 5) Medical foods are only to be used by patients in ongoing medical care. The records reviewed for the patient of concern do not indicate that any assessment of patient's nutritional needs was made, nor were the reasons for use of Trepadone discussed / documented. Without additional information on reason for need and given lack of evidence-based support for its use regardless, the Trepadone is not considered medically necessary for patient.