

Case Number:	CM14-0160543		
Date Assigned:	10/06/2014	Date of Injury:	10/18/2012
Decision Date:	10/30/2014	UR Denial Date:	08/29/2014
Priority:	Standard	Application Received:	09/30/2014

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. The expert reviewer is Board Certified in Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Texas. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 50 year old male who was injured at work on 10/18/2012. The injured worker is reported of experiencing exacerbation of neck, back and elbow pain. The physical examination revealed limitation of the range of motion of the neck and back. There was palpable tenderness of the paraspinal areas and the olecranon. The MRI of the Lumbar region was positive for spinal stenosis at L4-5; while the cervical MRI of 12/18/ 12 revealed disc diseases including neuroforaminal encroachment at C3-4, C4-5, as well as disc protrusions at C6-7, C3-4, and C5-6. The injured worker has been diagnosed of cervical strain; cervical myospasm; lumbar stenosis; lumbar spine herniated nucleus pulposis; Gastritis; Left elbow tendonitis, and left elbow sprain. Treatments include Aqua therapy; physical therapy; Diclofenac, Pantoprazole. At dispute are the requests for Theramine and Aptrim.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical

Evidence: <Physician Therapeutics><Theramine><http://www.ptlcentral.com/medical-foods-products.php>. < US Food and Drug Administration<Medical Foods Guidance Documents & Regulatory Information><<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/default.htm>>

Decision rationale: The injured worker sustained a work related injury on 10/18/2012. The medical records provided indicate the diagnosis of cervical strain; cervical myospasm; lumbar stenosis; lumbar spine herniated nucleus pulposus; Gastritis; Left elbow tendonitis, and left elbow sprain. Treatments include Aqua therapy; physical therapy; Diclofenac, Pantoprazole. The medical records provided for review do not indicate a medical necessity for Theramine. While the MTUS makes no reference to it, the Official Disability Guidelines recognizes it as a medical food, and like all medical foods recommends against it. The manufacturers of this product, Physician therapeutics, states as follows, "Theramine. A specially formulated prescription only Medical Food, consisting of a proprietary blend of amino acids and polyphenol ingredients in specific proportions, for the dietary management of altered metabolic processes associated with pain syndromes and inflammatory conditions" The FDA considers the medical foods as orphan formulated to be consumed or administered enterally under the supervision of a physician. The requested treatment is therefore not medically necessary and appropriate.

Apptrim: 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 Other Medical Treatment Guideline or Medical Evidence: < US Food and Drug Administration<Medical Foods Guidance Documents & Regulatory Information><<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/default.htm>> < Physician Therapeutics< Apptrim® ><http://www.ptlcentral.com/medical-foods-products.php>

Decision rationale: The injured worker sustained a work related injury on 10/18/2012. The medical records provided indicate the diagnosis of cervical strain; cervical myospasm; lumbar stenosis; lumbar spine herniated nucleus pulposus; Gastritis; Left elbow tendonitis, and left elbow sprain. Treatments include Aqua therapy; physical therapy; Diclofenac, Pantoprazole. The medical records provided for review do not indicate a medical necessity for Apptrim. While the MTUS makes no reference to it; the official Disability Guidelines recognizes it as a medical food, and like all medical foods recommends against it. The manufacturers of this product, Physician therapeutics, states as follows, " AppTrim capsules by oral administration. A specially formulated prescription only Medical Food, consisting of a proprietary formula of amino acids and polyphenol ingredients in specific proportions, for the nutritional management of the metabolic processes associated with obesity, morbid obesity, and metabolic syndrome" The FDA states, "The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "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." The medical necessity for this form of treatment is not established by the medical records reviewed.