

Case Number:	CM14-0179228		
Date Assigned:	11/03/2014	Date of Injury:	04/12/2013
Decision Date:	12/10/2014	UR Denial Date:	10/13/2014
Priority:	Standard	Application Received:	10/28/2014

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 Occupational Medicine and is licensed to practice in California. 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 patient is a 47 year-old male with a date of injury of 04/12/2013. The primary treating physician's progress report dated 09/30/2014 lists subjective complaints as pain in the left shoulder. The physician states that physical examination findings were unchanged from previous exam. No other objective findings were documented. The diagnoses include left shoulder impingement syndrome; pain in the left shoulder; cervical strain/sprain; neck pain; and myofascial syndrome. The medical records supplied for review document that the patient has been taking Trepadone for at least as far back as four months. Percura and Premier Pain Formula Ointment were first prescribed on 09/30/2014. The medications include Premier Pain Formula Ointment with Capsaicin SIG: TID; Trepadone, #120 SIG: two tablets po bid and Percura, #120 SIG: two tablets po bid.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Premier Pain Formula Ointment with Capsaicin: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: According to the MTUS Chronic Pain Medical Treatment Guidelines, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Premier Pain Formula Ointment with Capsaicin is not supported by the guidelines and is therefore not medically necessary.

120 Tablets of Trepadone: 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), Medical food

Decision rationale: Trepadone is a medical food thought to help with the management and relief of pain and inflammation related to joint disorders. Medical food is defined 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." Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Therefore, this request is not medically necessary.

120 Tablets of Percura: 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), Medical food

Decision rationale: Percura is a medical food product consisting of an amino acids mixture and is used in homeopathic medicine for clinical dietary management of the metabolic processes of pain, inflammation and loss of sensation due to peripheral neuropathy. Medical food is defined 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." Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Therefore, this request is not medically necessary.