

Case Number:	CM14-0059484		
Date Assigned:	07/09/2014	Date of Injury:	01/31/2013
Decision Date:	09/05/2014	UR Denial Date:	04/16/2014
Priority:	Standard	Application Received:	04/30/2014

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 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:

Patient is a 44 year-old female with date of injury 01/31/2013. The medical document associated with the request for authorization, a primary treating physician's progress report, dated 04/16/2014, lists subjective complaints as pain in the left shoulder and left elbow. Objective findings: Examination of the left shoulder revealed full range of motion with flexion. Positive Hawkin's test and Neer's test. Examination of the upper left extremities revealed positive Tinel's sign and positive elbow flexion test. AN MRI of the left shoulder done on 09/25/2013 was positive for subacromial subdeltoid bursitis. Diagnosis: 1. Status post left shoulder contusion with impingement syndrome 2. Left elbow medial and lateral epicondylitis 3. Possible carpal tunnel and or cubital tunnel syndrome 4. Gastrointestinal complaints. The medical records supplied for review document that the patient has been taking the following medication for at least as far back as 4 months. Medications: 1. Theramine (medical food) no SIG given 2. Topical Ibuprofen Cream SIG: apply to affected area 4 to 6 times per day.

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 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: Theramine is a Food and Drug Administration regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Theramine is thought to promote the production of the neurotransmitters that help manage and improve the sensory response to pain and inflammation. 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 entirely 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.

Topical Ibuprofen Cream: 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 Page(s): 111-112.

Decision rationale: According to the MTUS, 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, The efficacy in clinical trials for non-steroidal anti-inflammatory agents (NSAIDs) 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.