MAXIMUS Federal Services

Case Number:	CM14-0024497		
Date Assigned:	06/11/2014	Date of Injury:	11/01/1995
Decision Date:	07/15/2014	UR Denial Date:	02/17/2014
Priority:	Standard	Application Received:	02/26/2014

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 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 61 year old female whose date of injury is 11/01/95. There is no mechanism of injury in the submitted documentation. Subjective findings include bilateral wrist pain and left shoulder pain. The injured worker had an MRI of the left shoulder on 12/03/11 which showed a full thickness tear of the supraspinatus tendon. The injured worker had surgery on left shoulder (Mumford procedure) on 02/14/13, which resulted in an improvement after the procedure. The injured worker is utilizing medications to include Voltaren, Exalgo ER, Trazadone, Gabapentin, and Omeprazole. She did develop gastrointestinal reflux secondary to long term medication use. The pain is reported as 4/10 with medications and 10/10 without medications. The medications have reduced the pain level and increased function. The request is for Ketoflex (Ketoprofen 15%/Cyclobenzaprine 10%) cream, 240 grams.

IMR ISSUES, DECISIONS AND RATIONALES

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

ONE PRESCRIPTION OF KETOPFLEX (KETOPROFEN 15%/CYCLOBENZAPRINE 10%) CREAM 240GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Topical Compounding Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Compounded Medication.

Decision rationale: The CA MTUS, Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, as well as the US FDA do not recommend the use of compounded medication, as these medications are noted to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. Furthermore, the FDA requires that all components of a transdermal compounded medication be approved for transdermal use. The compound contains Ketoprofen and cyclobenzaprine which have not beem approved for transdermal use. Given the lack of supporting data from independent sources and without high quality studies published in peer-reviewed literature, this request is not indicated.