

Case Number:	CM14-0041016		
Date Assigned:	06/30/2014	Date of Injury:	10/08/2011
Decision Date:	08/25/2014	UR Denial Date:	03/10/2014
Priority:	Standard	Application Received:	04/08/2014

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 54-year-old male who has submitted a claim for unspecified internal derangement of knee and left knee meniscal tear associated with an industrial injury date of October 8, 2011. The medical records from 2012 through 2014 were reviewed, which showed that the patient complained of left knee pain. A physical examination revealed difficulty with bending and kneeling. Clicking and popping of the left knee were noted. McMurray's test was positive on the left. Tenderness over the medial joint line and crepitus were noted. The patient's range of motion was limited due to pain, and the sensation and motor strength were within normal limits. The patient's treatment to date has included arthroscopic surgery, physical therapy, acupuncture, steroid injections, and medications, which include Dendracin cream, Diclofenac, Zanaflex, Ibuprofen, Flexeril, and Ambien. The utilization review from March 10, 2014 denied the request for Ketoprofen with Lidocaine ultra cream, 240gm because the efficacy of topical analgesics in clinical trials has been inconsistent and most studies are small and of short duration. Ketoprofen is an agent not currently FDA approved for topical application and it has an extremely high incidence of photocontact dermatitis. There was also no note of any confounding medical issue or GI issue that would preclude the use of oral medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen with Lidocaine Ultracream, 240 gram, apply BID as needed: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 117-119.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: According to pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor antagonists). Compounded products have limited published studies concerning its efficacy and safety. There is little to no research as for the use of ketoprofen in compounded products. Ketoprofen is not FDA approved for topical application. Topical formulations of lidocaine and prilocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Furthermore, the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. In this case, the patient has been on the topical compounded product containing Ketoprofen and Lidocaine since August 2013. Compounded product was prescribed as adjuvant therapy for oral medications however, there was no discussion concerning the need for two different topical medications. In addition, certain components of this compounded product, such as Ketoprofen and Lidocaine, are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Furthermore, the request failed to specify the amount to be dispensed. Therefore, the request for Ketoprofen with Lidocaine ultra cream, 240 gram is not medically necessary.