

Case Number:	CM13-0034951		
Date Assigned:	12/11/2013	Date of Injury:	11/27/2007
Decision Date:	02/21/2014	UR Denial Date:	09/30/2013
Priority:	Standard	Application Received:	10/16/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology and Pain Medicine and is licensed to practice in Florida. 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 physician 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 53-year-old female who reported an injury on 11/27/2007 with a mechanism of injury being a slip and fall. The patient's diagnoses were noted to include status post C3 to C6 hybrid reconstruction 07/13/2012, lumbar discopathy, internal derangement right knee, bilateral shoulder pain, bilateral carpal tunnel syndrome, and left knee internal derangement secondary to persistent pain. The request was made for a transdermal medication as the patient was noted to be unable to take oral medications due to gastric bypass surgery.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 15%/ Lidocaine 1%/ Capsaicin 0.125%/ Tramadol 5% Spray refill: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gillman's The Pharmacological Basis of Therapeutics 11th ed. McGraw Hill, 2006; Physician's Desk Reference 65th ed.; www.RxList.com; ODG Workers Compensation Drug Formulary; drugs.com; Epocrates Online; Monthly Prescribing Reference; Opioid Dose Calcul

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 82, 111-112.

Decision rationale: California MTUS indicates Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety ... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended ... There is no peer-reviewed literature to support the use of topical baclofen...Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application...Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments ... a thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. The clinical documentation submitted for review, while indicating the patient could not take oral medications due to gastric bypass, failed to include the efficacy of the medication. It failed to document exceptional factors to support the use of the topical medication as many of the medications in the requested compound are not FDA approved and per California MTUS Guidelines, any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Given the above and the lack of documentation of exceptional factors to warrant adherence to California MTUS Guidelines and FDA Guidelines, the request for Ketoprofen 15%/ Lidocaine 1%/ Capsaicin 0.125%/ Tramadol 5% Spray refill is not medically necessary.