MAXIMUS Federal Services

Case Number:	CM13-0052983		
Date Assigned:	12/30/2013	Date of Injury:	01/16/2002
Decision Date:	03/18/2014	UR Denial Date:	10/28/2013
Priority:	Standard	Application Received:	11/18/2013

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 Internal Medicine, has a subspecialty in Pulmonary Disease 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 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 52-year-old female who reported injury on 01/16/2002. The mechanism of injury was not provided. The patient was noted to be in the office for medication refills. The patient's diagnosis was noted to be contusion/hematoma and lumbosacral joint ligament sprain. The patient indicated no significant change in her condition since the last office visit and was noted to be using 30 gm of Flurbiprofen 25% topical cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 25% topical cream: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen Section and Topical Analgesics Section Page(s): 72,111.

Decision rationale: The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The clinical documentation submitted for revealed failed to indicate the patient had neuropathic pain and that she had trialed and failed antidepressants and anticonvulsants. Additionally, this medication is not FDA approved. There was lack of documentation indicating a necessity for 2 medications with Flurbiprofen. The request as submitted failed to indicate the quantity of medication being requested. Given the above, the request for Flurbiprofen 25% topical cream is not medically necessary.

Flurbiprofen/Lidocaine topical cream: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section,Flurbiprofen Section and Lidocaine Section Page(s): 111,72,112.

Decision rationale: The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. 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. The clinical documentation submitted for review failed to indicate the patient had neuropathic pain and had trialed and failed antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity for 2 topical creams containing Flurbiprofen. There was lack of documentation indicating exceptional factors to warrant non-adherence to FDA and guideline recommendations. The request as submitted failed to indicate the quantity of Flurbiprofen/Lidocaine topical cream that was being requested. Given the above, the request for Flurbiprofen Lidocaine topical cream is not medically necessary.