

Case Number:	CM13-0015358		
Date Assigned:	10/07/2013	Date of Injury:	08/07/2012
Decision Date:	01/21/2014	UR Denial Date:	08/01/2013
Priority:	Standard	Application Received:	08/22/2013

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:

This patient is a 63-year-old female who reported an injury on August 07, 2012. The documentation submitted for review indicates that the patient has complaints of an injury regarding the back, right ankle, right leg, neck, feet, legs, hands, knee and shoulders. The notes indicate that the patient was injured on August 07, 2012 after tripping on a plastic mat and falling forward and catching herself on the edge of a table. A prior review was submitted that indicates that the patient was being treated with a pain management physician who, on July 05, 2013, made a request for authorization for cyclobenzaprine, capsaicin, and lidocaine and Flurbiprofen cream as well as a request for ketoprofen, lidocaine, tramadol and capsaicin cream. However, the clinical note was not submitted for this review.

IMR ISSUES, DECISIONS AND RATIONALES

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

The retrospective request for Cyclobenzaprine 2%, Capsaicin 0.0125, Lidocaine 1%, Flurbiprofen 2%, 120mL, with three (3) refills: 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 Page(s): 111-113.

Decision rationale: The California MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. 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. The CA MTUS states that nonsteroidal anti-inflammatory agents have limited demonstrated efficacy in clinical trials and have been inconsistent, with most studies being small and of short duration. The CA MTUS states that muscle relaxants are not recommended as there is no evidence for the use of any other muscle relaxant as a topical product. The CA MTUS states that capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. The CA MTUS states that lidocaine in a transdermal application is recommended for neuropathic pain and recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy such as a tricyclic or Serotonin-norepinephrine reuptake inhibitors (SNRIs) antidepressant or an Antiepileptic drugs (AEDs), such as gabapentin or Lyrica. No other commercially approved topical formulations of lidocaine, whether creams, lotions or gels, are indicated for neuropathic pain. In February 2007, the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. While the documentation submitted for review indicates that this patient is currently prescribed the requested gel/cream as part of pain management treatment, the request is not supported as guidelines indicate that cyclobenzaprine, a muscle relaxant, is not recommended as there is no evidence of the use of any muscle relaxant as a topical product. Given the above, the retrospective request for cyclobenzaprine 2%, capsaicin "0.0125," lidocaine 1% and flurbiprofen 2% at 120 mL with 3 refills is not medically necessary or appropriate.

The retrospective request for Ketoprofen 15%, Lidocaine 1%, Tramadol 5%, Capsaicin 0.0125%, 120mL with three (3) refills: 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 Page(s): 111-113. Decision based on Non-MTUS Citation Medical Evidence: Effectiveness of topical administration of opioids in palliative care: a systematic review B LeBon, G Zeppetella, IJ Higginson - Journal of pain and symptoms, 2009 - Elsevier.

Decision rationale: The CA MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include a lack of systemic side effects, absence of drug interactions and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no

research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. 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. The CA MTUS states that ketoprofen is a non-FDA-approved agent. The CA MTUS does not specifically address opioid analgesics in topical formulations. However, peer-reviewed literature states that there is a deficiency of higher quality evidence on the role of topical opioids and that more robust primary studies are required to inform practice recommendations. The CA MTUS states that capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. While the documentation submitted for review indicates that this patient is currently prescribed the requested cream/gel as part of a pain management regimen, the guidelines do not support the use of ketoprofen as it is not recommended per the FDA Guidelines due to an extremely high incidence of photocontact dermatitis. Furthermore, tramadol, a synthetic opioid, is not supported for topical administration by clinical literature, as there is a deficiency of higher quality evidence on the role of topical opioids, requiring more robust primary studies to inform practice recommendations. Given the above, the retrospective request for ketoprofen 15%, lidocaine 1%, tramadol 5%, capsaicin 0.0125% at 120 mL with 3 refills is not medically necessary or appropriate.