

Case Number:	CM14-0023794		
Date Assigned:	06/11/2014	Date of Injury:	04/24/2013
Decision Date:	07/15/2014	UR Denial Date:	02/12/2014
Priority:	Standard	Application Received:	02/25/2014

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 and Emergency 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 53 year-old with a date of injury of 04/24/13. A progress report associated with the request for services, dated 01/31/14, identified subjective complaints of pain and burning in the right lower extremity. Objective findings included scarring of the lower extremities with hypersensitivity to touch. There was hypertrophy in the superior aspect. Diagnoses included late effects of burns to the lower extremities. Treatment has included intra-lesional steroid injections. The patient also takes Celebrex. A Utilization Review determination was rendered on 02/12/14 recommending non-certification of "topical compound pain cream: diclofenac 10%, ketamine 10%, gabapentin 10%, lidocaine 10% (prescribed 1-31-14)".

IMR ISSUES, DECISIONS AND RATIONALES

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

TOPICAL COMPOUND PAIN CREAM, DICLOFENAC 10%, KETAMINE 10%, GABAPENTIN 10%, LIDOCAINE 10% (PRESCRIBED 1-31-14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, TOPICAL ANALGESICS.

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they 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." Diclofenac 10% is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and of short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also indicate that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. Gabapentin 10% is an anti-epilepsy drug. The MTUS Guidelines indicate that gabapentin is: "Not recommended. There is no peer-reviewed literature to support use." The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, there is no documented medical necessity for the addition of gabapentin in the topical formulation for this injured worker. Lidocaine 10% is a topical anesthetic. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. Ketamine 10% is under study and only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore there is no documentation supporting the medical necessity of the compounded formulation.