

Case Number:	CM14-0028821		
Date Assigned:	06/20/2014	Date of Injury:	07/02/2013
Decision Date:	07/17/2014	UR Denial Date:	02/20/2014
Priority:	Standard	Application Received:	03/06/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in Illinois. 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 injured worker is a 49-year-old female with a reported injury on 07/02/2013. The mechanism of injury was not provided within the clinical notes. The clinical note dated 01/17/2014 reported that the injured worker complained of bilateral upper extremity, neck, and back pain. The physical examination of the injured worker's right elbow revealed tenderness to the medial and lateral epicondyles and olecranon process. Tinel's sign was present to the right antecubital, radial nerve, and ulnar nerve. Phalen's test was positive to the right. It was reported that the injured worker's motor power was weak in the right elbow and right shoulder. The range of motion of the injured worker's right elbow demonstrated flexion to 120 degrees and extension to 180 degrees. The range of motion of the injured worker's right forearm demonstrated supination to 70 degrees and pronation to 70 degrees. The injured worker's diagnoses included bilateral upper extremity overuse tendinopathy and bilateral elbow epicondylitis. The provider requested Tylenol with codeine, compound cream consisting of amitramadol DM ultra cream and gabaketolido cream. The rationale for the requested medications was not provided within the clinical documentation. The Request for Authorization was submitted on 02/27/2014. The injured worker's prior treatments were not included in the clinical note.

IMR ISSUES, DECISIONS AND RATIONALES

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

APAP W/CODIENE 300/60 MG QTY 60; ONE BY MOUTH EVERY 6 TO 8 HOURS AS NEEDED: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Management.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list, Opioids, criteria for use Page(s): 92, 78.

Decision rationale: The request for APAP with codeine 300/60 mg quantity: 60, 1 by mouth every 6 to 8 hours as needed is not medically necessary. The injured worker complained of neck and back pain. The treating physician's rationale for Tylenol with codeine was not provided within the clinical note. The CA MTUS guidelines recognize codeine in combination with acetaminophen is classified as a schedule III medication. The guidelines recommend that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. The guidelines recognize four domains that have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. There is a lack of clinical information provided documenting the efficacy of Tylenol with codeine as evidenced by decreased pain and significant objective functional improvements. Moreover, there is a lack of documentation that the injured worker has had urine drug screens to validate proper medication adherence in the submitted paperwork. Given the information provided, there is insufficient evidence to determine appropriateness to warrant medical necessity; as such, the request is not medically necessary.

COMPOUND CREAM AMITRAMADOL DM ULTRACREAM 4%/20%/10% 240 MG:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation 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/Wiley Online Library, High Doses of Topical Amitriptyline in Neuropathic Pain: Two Cases and Literature Review -David J. Kopsky MD and Jan M. Keppel Hesselink MD, MSc, PhD <http://onlinelibrary.wiley.com/images/wolSiteLogo.png>.

Decision rationale: The request for compound cream amitramadol DM ultra cream 4/20/10% 240 mg is non-medically necessary. The injured worker complained of neck and back pain. The treating physician's rationale for compound cream was not provided within the clinical notes. 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 Wiley online library states that high dose topical amitriptyline 5% and 10% might be a useful adjunct to treat severe and intractable neuropathic pain. Although previous trials were inconsistent in reporting efficacy of topical amitriptyline cream, in a dose range from 1% to 5%, we believe the dose range has to be further explored, targeting the lowest

therapeutic plasma concentration of amitriptyline. Further randomized double-blind studies, including full plasma sampling are needed to substantiate our findings. There is a lack of information provided documenting the efficacy of the compound topical medication as evidenced by decreased pain and significant objective functional improvements. Moreover, there is a lack of clinical research indicating that topical amitriptyline cream is effective on pain and discomfort. Furthermore, the requesting provider did not specify the utilization frequency and location of application of the medication being requested. As such, the request is not medically necessary.

**COMPOUND CREAM GABAKETOLIDO CREAM GABAPENTIN, 5%
KETOPROFEN, 20% LIDOCAINE hcl 6.15% 240 MG: 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 request for compound cream gabaketolido cream gabapentin 5%, Ketoprofen 20%, lidocaine HCL 6.15%, 240 mg is not medically necessary. The injured worker complained of neck and back pain. The treating physician's rationale for compound medicated cream was not provided within the clinical documentation. The CA MTUS guidelines recommend lidocaine for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. 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 guidelines do not recommend topical gabapentin. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend gabapentin for topical utilization. Per the guidelines, no other commercially-approved topical formulation of lidocaine (whether cream, lotion, or gel) are indicated for neuropathic pain. Therefore, the combination of lidocaine with any other topical medication is not recommended. The guidelines state that any compound product that contains at least 1 drug (or drug class) that is not recommended is not recommended. As such, the request is not medically necessary.