

Case Number:	CM13-0046149		
Date Assigned:	12/27/2013	Date of Injury:	09/05/2012
Decision Date:	03/12/2014	UR Denial Date:	10/28/2013
Priority:	Standard	Application Received:	11/12/2013

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 & 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 67 year-old with a date of injury of 09/05/12. A progress report included by [REDACTED] dated 10/02/13, identified subjective complaints of neck, low back, and knee pain. Objective findings included normal range-of-motion of the cervical spine and negative compression test. There was a positive straight leg-raising on the right but with preserved motor function. Reflexes were absent. Diagnoses have included cervical and lumbar strain with radiculopathy and right knee lateral meniscus tear. Treatment has included physiotherapy, chiropractic, acupuncture, and oral medications. Current oral medications included an NSAID, Flexeril, and omeprazole. There is no mention of response or past failed oral therapies. Topical therapy appeared to be new. A Utilization Review determination was rendered on 10/28/13 recommending non-certification of "CMPD-Flurbipro/Lidocaine/Amitripty/PCCA Lipa day supply 20 qty 180 refills and CMPD-Gabapenti/Cyclobenz/Tramadol/PCCA Lipo Day supply 20: 180 refills".

IMR ISSUES, DECISIONS AND RATIONALES

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

CMPD-Flurbipro/Lidocaine/Amitripty/PCCA Lipa day supply 20 qty 180 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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; and Clin J Pain. 2008 Jan;24(1):51-5.

Decision rationale: The Physician Reviewer's decision rationale: The requested compound (CMPD) consists of flurbiprofen, an NSAID (Non-steroidal anti-inflammatory drug), lidocaine, an anesthetic, and amitriptyline, a tricyclic antidepressant, with the delivery vehicle Lipoderm, a product of the Professional Compounding Centers of America (PCCA). The California Medical Treatment Utilization Schedule (MTUS) states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The Official Disability Guidelines (ODG) state that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The efficacy of topical NSAIDs in osteoarthritis has been inconsistent. 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 state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. In neuropathic pain, they are not recommended as there is no evidence to support their use. The only FDA approved topical NSAID is diclofenac. 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 necessity for the addition of flurbiprofen in the topical formulation for this patient. 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. 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 demonstrated medical necessity for lidocaine with this type of formulation. Neither the California Medical Treatment Utilization Schedule (MTUS) nor the Official Disability Guidelines (ODG) specifically addresses the use of amitriptyline as a topical agent. A randomized, placebo-controlled crossover study examined topical 5% amitriptyline with 5% lidocaine topical in patients with neuropathic pain. The study found that topical amitriptyline was not effective. Therefore, there is no demonstrated medical necessity for topical amitriptyline.

CMPD-Gabapenti/Cyclobenz/Tramadol/PCCA Lipo Day supply 20: 180 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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; and www.updates.pain-topics.org; J Anesth. 2010 Oct;24(5):705-8.

Decision rationale: The requested compound (CMPD) consists of gabapentin, an anti-seizure agent, cyclobenzaprine, a muscle relaxant, and tramadol, a centrally acting opioid analgesic, with the delivery vehicle Lipoderm, a product of the Professional Compounding Centers of America

(PCCA). The California Medical Treatment Utilization Schedule (MTUS) states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The Official Disability Guidelines (ODG) state that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The MTUS Guidelines state 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 patient. The MTUS Guidelines state that there is no evidence for baclofen or any other muscle relaxant as a topical product. 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 necessity for the addition of cyclobenzaprine in the topical formulation for this patient. The efficacy of topical Tramadol is not specifically addressed in the MTUS or the ODG. There is some data that topical Tramadol has efficacy directly at an acute postsurgical site. However, there is insufficient data to assure that significant systemic absorption does not occur. Lacking definitive data on the efficacy of topical Tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy. Therefore, medical necessity for topical Tramadol has not been established