

Case Number:	CM13-0060890		
Date Assigned:	12/30/2013	Date of Injury:	07/18/2011
Decision Date:	05/23/2014	UR Denial Date:	11/18/2013
Priority:	Standard	Application Received:	12/03/2013

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 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 44 year-old with a date of injury of 07/18/11. A progress report associated with the request for services, dated 11/05/13, identified subjective complaints of lumbar spine pain. Objective findings included tenderness, lumbar spasm and pain with range-of-motion. Diagnoses included lumbosacral discopathy. Treatment has included acupuncture, muscle relaxants, oral and topical analgesics. A Utilization Review determination was rendered on 11/18/13 recommending non-certification of "Gabacyclotram bid-tid 60g, days 30 and Flurbiprofen tid 120g, days.

IMR ISSUES, DECISIONS AND RATIONALES

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

GABACYCLTRAM BID-TID 60G, DAYS 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SECTION TOPICAL ANALGESICS Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SECTION TOPICAL ANALGESICS Page(s): 111-113. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, TOPICAL ANALGESICS; and the website WWW.UPDATE.PAIN-TOPICS.ORG; J ANESTH. 2010 OCT;24(5):705-8.

Decision rationale: The requested compound consists of gabapentin, an anti-seizure agent, cyclobenzaprine, a muscle relaxant, and tramadol, a centrally acting opioid analgesic. The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines indicate that topical analgesics are recommended as an option in specific circumstances. However, they do indicate 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." 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 employee. The MTUS Guidelines indicate that there is no specific 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 employee. The efficacy of topical Tramadol is not specifically addressed in the MTUS or the Official Disability Guidelines (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. 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 the medical necessity of the compounded formulation.

FLURBIP TID 120G, DAYS 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SECTION TOPICAL ANALGESICS Page(s): 111.

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." Flurbiprofen 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 do not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is diclofenac. In this case, there is no documentation of the failure of conventional therapy or documented functional improvement for the medical necessity of flurbiprofen as an NSAID topical agent.