

Case Number:	CM13-0010968		
Date Assigned:	09/23/2013	Date of Injury:	11/19/2012
Decision Date:	11/13/2014	UR Denial Date:	08/02/2013
Priority:	Standard	Application Received:	08/14/2013

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 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 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:

This patient is a 46-year-old with a date of injury of 11/19/2012. A progress report associated with the request for services, dated 07/02/2013, identified subjective complaints of right knee pain. Objective findings included tenderness to palpation of the right knee and associated muscle spasms. Diagnoses (paraphrased) included right knee meniscus tear and sprain/strain of the right knee. Treatment had included oral analgesics. A Utilization Review determination was rendered on 08/02/2013 recommending denial of "prescription of compound medication: 240gr Capsaicin 0.025%, Flurbiprofen 20%, tramadol 10%, menthol 2%, camphor 2% and prescription request for compound medication: 240gr Flurbiprofen 20%, Tramadol 20%".

IMR ISSUES, DECISIONS AND RATIONALES

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

PRESCRIPTION OF COMPOUND MEDICATION: 240GR CAPSAICIN 0.025%, FLURBIPROFEN 20%, TRAMADOL 10%, MENTHOL 2%, CAMPHOR 2%: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 398, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics

Other Medical Treatment Guideline or Medical Evidence: www.updates.pain-topics.org; J Anesth. 2010 Oct;24(5):705-8.

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." Menthol is a topical form of cryotherapy. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of menthol for chronic pain. Capsaicin 0.025% is an active component of chili peppers and acts as an irritant. The Guidelines for Chronic Pain state that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) state that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. Tramadol 10% is an opioid analgesic being used as a topical agent. 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. Flurbiprofen 20% is a non-steroidal anti-inflammatory drug (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 state 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. The only FDA approved topical NSAID is Diclofenac. In this case, considering its moderate to poor efficacy, there is no documentation of the failure of conventional therapy for the medical necessity of capsaicin topical. Also, lacking definitive data on the efficacy of topical tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy or other compelling reason for its 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, in this case, there is no documentation of the failure of conventional therapy, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation.

**PRESCRIPTION REQUEST FOR COMPOUND MEDICATION: 240GR
FLURBIPROFEN 20%, TRAMADOL 20%: 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 Other Medical Treatment Guideline or Medical Evidence: www.updates.pain-topics.org; J Anesth. 2010 Oct;24(5):705-8.

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." Tramadol 20% is an Opioid analgesic being used as a topical agent. 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. Flurbiprofen 20% 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 state 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. The only FDA approved topical NSAID is diclofenac. Lacking definitive data on the efficacy of topical tramadol and flurbiprofen, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy or other compelling reason for its use. Therefore, there is no documentation for the medical necessity for Topical Tramadol/Flurbiprofen.

