

Case Number:	CM13-0038562		
Date Assigned:	12/18/2013	Date of Injury:	07/18/2011
Decision Date:	04/28/2014	UR Denial Date:	10/11/2013
Priority:	Standard	Application Received:	10/25/2013

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:

The patient is a 50-year-old woman who was injured at work on July 18, 2011. The patient was evaluated on September 25, 2013. The patient had subjective complaints of neck and low back pain. She had radicular symptoms into both upper extremities. Physical exam revealed tenderness to palpation and decreased range of motion of the neck and low back. Diagnoses included cervical and lumbar disc disease. Recommendations were for epidural steroid injections and topical analgesics. Request was made for treatment with a cream containing ketoprofen 10%, cyclobenzaprine 3%, lidocaine, 3%, 5% PCCA Lipoderm base and Flurbiprofen 10%/ Capsaicin 0.025%/ Menthol 2%/ Camphor 1%/ Ultraderm base cream. This request was noncertified on 10/11/13.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 10%/ Cyclobenzaprine 3%/ Lidocaine HCL 5%/ PCCA Lipoderm base - DOS 1/21/2013: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) .

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Topical Analgesics. Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

Decision rationale: The 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. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Ketoprofen 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 or 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). The only FDA approved topical NSAID is diclofenac. Ketoprofen is not approved and "... has an extremely high incidence of photo contact dermatitis and photosensitization reactions." Cyclobenzaprine 2% is a muscle relaxant being used as a topical analgesic. The MTUS Guidelines specifically state that there is no evidence for baclofen or any other muscle relaxant as a topical product. Therefore, there is no necessity for the addition of cyclobenzaprine in the topical formulation for this patient. Lidocaine 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. 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 documented functional improvement, and recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation.

Flurbiprofen 10%/ Capsaicin 0.025%/ Menthol 2%/ Camphor 1%/ Ultraderm base cream - DOS 1/21/2013: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) .

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Topical Analgesics. Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

Decision rationale: The 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 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 Final Determination Letter for IMR Case Number CM13-

0038562 4 small and or 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). The only FDA approved topical NSAID is diclofenac. 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 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. Considering its moderate to poor efficacy, there is no documented functional improvement for the medical necessity of the compounded ingredients. 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, the record does not document the medical necessity of the compounded formulation.