

Case Number:	CM13-0046860		
Date Assigned:	12/27/2013	Date of Injury:	11/17/2009
Decision Date:	04/25/2014	UR Denial Date:	11/05/2013
Priority:	Standard	Application Received:	11/12/2013

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 28 year-old with a date of injury of 11/17/09. A progress report associated with the request for services, dated 08/07/13, identified subjective complaints of low back pain that sometimes radiates down both legs. Objective findings included tenderness to palpation of the lumbar spine and a positive straight leg-raising on the right side. Sensory and motor function was normal. Diagnoses included lumbar disc disease with radiculopathy and past right wrist, elbow and shoulder strain/sprain. Treatment at that time was ibuprofen. Past therapy included physical therapy, acupuncture, and epidural steroid injections. A 09/24/13 psychological examination deemed the patient to be in a poor prognosis category for spine surgery outcomes. A Utilization Review determination was rendered on 11/05/13 recommending non-certification of "KETOP/LIDOC/CAP/TRAM, #180; CYCLO/CAPS/LID/KETOP 120MG, #1".

IMR ISSUES, DECISIONS AND RATIONALES

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

KETOP/LIDOC/CAP/TRAM, #180: 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 based on Non-MTUS Citation OFFICIAL

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 15% 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). The only FDA approved topical NSAID is diclofenac. Ketoprofen is not approved and "... has an extremely high incidence of photocontact dermatitis and photosensitization reactions." Lidocaine 1% 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. Capsaicin has shown success in musculoskeletal conditions. 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. They are recommended only as an option in patients who have not responded or are intolerant to other treatments. It is further noted that a 0.025% formulation is available for treatment of osteoarthritis and a 0.075% formulation for neuropathic pain. The requested strength in this formulation is 0.012%. Tramadol 5% is an opioid analgesic being used as a topical agent. 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. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, there are ingredients in the compound not recommended and therefore no medical necessity for the compounded formulation.

CYCLO/CAPS/LID/KETOP 120MG, #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN, TOPICAL ANALGESICS.

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 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. Ketoprofen is not approved and "... has an extremely high incidence of photocontact dermatitis and photosensitization reactions." 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. Capsaicin is an irritant that is the active component of chili peppers. 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) states that neither salicylates nor capsaicin show efficacy in the treatment of osteoarthritis. Capsaicin is available as a 0.025% formulation (for the treatment of osteoarthritis) and a 0.075% formulation primarily from studies for neuropathic pain. However, the Guidelines specifically state that: "... there have been no studies of 0.0375% formulation of capsaicin and there is no current indication th