

Case Number:	CM14-0089010		
Date Assigned:	07/23/2014	Date of Injury:	04/04/2011
Decision Date:	10/01/2014	UR Denial Date:	05/19/2014
Priority:	Standard	Application Received:	06/12/2014

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, has a subspecialty in 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 case involves a 50 year-old with a date of injury of 04/04/11. A progress report associated with the request for services, dated 09/15/11, was reported to note subjective complaints of right shoulder, neck, and arm pain. There was associated numbness in the right arm. Objective findings included tenderness to palpation of the cervical spine with decreased range of motion. Treatment had included chiropractic, physical therapy and oral and topical medications. A Utilization Review determination was rendered on 05/18/14 recommending non-certification of "retrospective request for 60 Tylenol 3 (Codeine APAP) 30-300 mg between 9/22/2011 and 9/22/2011; retrospective request for 30 Zanaflex (Tizanidine hcl) 4 mg between 9/22/2011 and 9/22/2011; retrospective request for 1 compound cream: Capsaicin 0.0375 %, Menthol 2%, Camphor 2 %, Tramadol 15 %, Pencream between 9/15/2011 and 9/15/2011 and retrospective request for 1 compound cream: Diclofenac 30 % Pencream between 9/15/2011 and 9/15/2011".

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for 60 Tylenol I3 (Codiene APAP) 30-300 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CHRONIC PAIN MEDICAL TREATMENT GUIDELINES .

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 181,Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Tylenol #3 is a combination of the opioid codeine and acetaminophen. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." or necessity of therapy beyond 16 weeks due to specific functional improvement. In this case, there is no documentation of the elements of the pain assessment referenced above or the length of intended use in the records submitted. Since the evidence is unclear for the value of opioids, there is no documented medical necessity for Tylenol #3. As such, this request is not medically necessary.

Retrospective request for 30 Zanaflex (Tizanidine Hcl) 4 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CHRONIC PAIN MEDICAL TREATMENT GUIDELINES .

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-66.

Decision rationale: Tizanidine (Zanaflex) is a centrally acting alpha₂-adrenergic agonist antispasticity/antispasmodic muscle relaxant. It is approved for spasticity and unlabeled use for low back pain. Dosage recommended is 2-4 mg every eight hours up to a maximum of 36 mg per day. The Medical Treatment Utilization Schedule (MTUS) states that muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. However, eight studies have shown efficacy of Tizanidine for low back pain (Chou 2007). Other authors recommend Tizanidine as a first-line option to treat myofascial pain. It may also provide benefit as an adjunct treatment for fibromyalgia. There are no recommendations given for neck pain. Therefore, in this case, the Guidelines do not give a recommendation for the area being treated and the dosing of the drug was not specified. As such, this request is not medically necessary.

Retrospective request for 1 compound cream: Capsaicin 0.0375 %, Menthol 2%, Camphor 2 %, Tramadol 15 %, Pencream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CHRONIC PAIN MEDICAL TREATMENT GUIDELINES .

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, 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." Pencream is a compounding agent. 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 0.0375% 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. 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 that this increase over a 0.025% formulation would provide any further efficacy." Tramadol 15% 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. 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 or the 0.375% formulation. 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, documented functional improvement, or recommendation for all the ingredients of the compound and therefore, this request is not medically necessary.

Retrospective request for 1 compound cream: Diclofenac 30 % Pencream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CHRONIC PAIN MEDICAL TREATMENT GUIDELINES .

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." Voltaren (Diclofenac) 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 Food and Drug Administration (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 Voltaren (Diclofenac) as an NSAID topical agent. Likewise, the request is for an indication for which there is little evidence of benefit (cervical spine). Therefore, the medical record does not document the medical necessity for Diclofenac topical.