

Case Number:	CM13-0030096		
Date Assigned:	04/23/2014	Date of Injury:	11/17/2009
Decision Date:	05/21/2014	UR Denial Date:	09/18/2013
Priority:	Standard	Application Received:	09/26/2013

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 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 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 43 year-old with a date of injury of 11/17/09. The most recent progress report that was associated with the request for services, dated 07/22/13, identified subjective complaints of what was the diagnosis - carpal tunnel syndrome. The record states that cervical and lumbar symptomatology had not changed. There was also mention of headaches. It was noted that he takes naproxen but it causes an upset stomach. Objective findings included tenderness to palpation of the cervical spine with decreased range-of-motion. Dysesthesia was noted at C5 and C6. Phalen's and Tinel's signs were positive on the right. There was also tenderness of the lumbar spine and dysesthesia in the L5 dermatome. Diagnoses included cervical and lumbar discopathy; cervicalgia; and bilateral carpal tunnel syndrome. Treatment has included NSAIDs, muscle relaxants, oral opioids, anti-nausea medication, and topical analgesics. A Utilization Review determination was rendered on 09/17/13 recommending non-certification of "cyclobenzaprine 7.5mg, #120; ondansetron ODT 4mg, #60; and Medrox patches #30".

IMR ISSUES, DECISIONS AND RATIONALES

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

CYCLOBENZAPRINE 7.5MG, #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CYCLOBENZAPRINE (FLEXERIL),.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
CYCLOBENZAPRINE (FLEXERIL®)/ MUSCLE RELAXANTS Page(s): 41-42, 63-66.

Decision rationale: Cyclobenzaprine is an antispasmodic muscle relaxant. 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. They note that in most low-back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The MTUS states that cyclobenzaprine is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for cyclobenzaprine for chronic use. Though it is noted that cyclobenzaprine is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. They further state that treatment should be brief and that addition of cyclobenzaprine to other agents is not recommended. The Guidelines do note that cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. The record does not show any evidence of fibromyalgia, and other indications for cyclobenzaprine beyond a short course are not well supported. Likewise, it is being used in combination with other agents; particularly NSAIDs for which no additional benefit has been shown. Therefore, in this case, the medical record does not document the medical necessity for cyclobenzaprine.

ONDANSETRON ODT 4MG, #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: Ondansetron is a serotonin 5-HT₃ receptor antagonist used for the treatment of nausea. The Medical Treatment Utilization Schedule (MTUS) does not address the use of antiemetics or ondansetron specifically. The Official Disability Guidelines (ODG) state that ondansetron is not recommended for nausea and vomiting secondary to opioid use. Likewise, it is only FDA- approved for nausea and vomiting secondary to chemotherapy, postoperative use, and gastroenteritis. The medical record does not document any of the above indications and therefore the medical necessity for Ondansetron in this case is non certified.

MEDROX PATCHES #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
CAPSAICIN, TOPICAL; SALICYLATE TOPICALS; TOPICAL ANALGESICS Page(s): 28-29, 105, 111-113. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL

TREATMENT GUIDELINES, CAPSAICIN, TOPICAL; SALICYLATE TOPICALS;
TOPICAL ANALGESICS, 28-29; 105; 111-113

Decision rationale: Medrox has multiple ingredients that include methyl salicylate 20%, capsaicin 0.0375%, and menthol USP 5%. 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." The Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. 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. It is further noted that 0.025% formulation is available for treatment of osteoarthritis and 0.075% formulation for neuropathic pain. They state that there have been no studies of the 0.0375% formulation and no current indication that the increase over the 0.025% formulation would provide any further efficacy. The Official Disability Guidelines (ODG) states that neither salicylates nor capsaicin has shown any efficacy in the treatment of osteoarthritis. 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. 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 or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation, Medrox is non certified.