

Case Number:	CM13-0011908		
Date Assigned:	06/06/2014	Date of Injury:	07/06/2012
Decision Date:	07/24/2014	UR Denial Date:	07/12/2013
Priority:	Standard	Application Received:	08/15/2013

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 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 57 year-old with a date of injury of 07/06/12. A progress report associated with the request for services, dated 07/01/13, identified subjective complaints of low back pain and left shoulder pain. Objective findings included tenderness to palpation of the low back and left shoulder. There was pain with range-of-motion of both. Dysesthesia was noted in the L5 and S1 dermatomes. Diagnoses included lumbar discopathy and internal derangement of the left shoulder. Treatment has included NSAIDs that are noted to provide temporary relief allowing him to perform activities of daily living. However, they also cause an upset stomach.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen sodium 550mg #120: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Acetaminophen; NSAIDs Page(s): 12; 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back, NSAIDs.

Decision rationale: Naproxen (Naprosyn) is a non-steroidal anti-inflammatory agent (NSAID). The Medical Treatment Utilization Schedule (MTUS) states that NSAIDs are recommended for

use in osteoarthritis. It is noted that they are: "Recommended at the lowest dose for the shortest period in patients with moderate to severe pain." They further state that there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. The Official Disability Guidelines (ODG) state that studies have found that NSAIDs have more side effects than acetaminophen or placebo, but less than muscle relaxants or narcotic analgesics. Another study concluded that NSAIDs should be recommended as a treatment option after acetaminophen. The non-certification was based upon lack of recommended use of NSAIDs for chronic pain control. However, the MTUS states that acetaminophen and NSAIDs are both recommended as first-line therapy for chronic low back pain. In this case, there is documentation of chronic low back pain with some functional improvement from naproxen and therefore medical necessity.

Omeprazole DR 20mg #120: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

Decision rationale: The recommendations for NSAID-induced dyspepsia include changing to another NSAID, or treatment with an H₂-receptor antagonist or a proton pump inhibitor. The non-certification was based upon lack of any risk factors that would justify prophylaxis. However, in this case, there is documentation of NSAID-induced gastrointestinal symptoms and the request is for active treatment rather than prophylaxis. Therefore, the medical record does document the medical necessity for omeprazole.

Ondansetron ODT 8mg #30 with two refills: 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 antiemetic's or Zofran 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.

Cyclobenzaprine hydrochloride 7.5mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; Muscle Relaxants Page(s): 41-42; 63-66.

Decision rationale: Cyclobenzaprine is an antispasmodic muscle relaxant. The Medical Treatment Utilization Schedule (MTUS) states 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. The patient has been on cyclobenzaprine for a prolonged period. Likewise, it has not been prescribed in the setting of an acute exacerbation of symptoms. Therefore, based upon the Guidelines, the record does not document the further medical necessity for cyclobenzaprine.

Medrox pain relief ointment: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, 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 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 a 0.025% formulation is available for treatment of osteoarthritis and a 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 documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation, Medrox.

Tramadol hydrochloride ER 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Opioids; Tramadol Page(s): 74-96; 113.

Decision rationale: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic. 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 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)." Opioids are not recommended for more than 2 weeks and the Guidelines further state that tramadol is not recommended as a first-line oral analgesic. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy in view of

the recommendations to avoid long-term therapy; likewise, that other first-line oral analgesics have been tried and failed. Therefore, the record does not document the medical necessity for tramadol.