

Case Number:	CM14-0108954		
Date Assigned:	08/01/2014	Date of Injury:	03/26/2011
Decision Date:	09/24/2014	UR Denial Date:	06/19/2014
Priority:	Standard	Application Received:	07/14/2014

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 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 48 year-old with a date of injury of 03/26/11. A progress report associated with the request for services, dated 05/12/14, identified subjective complaints of back and right hip pain. Objective findings included tenderness to palpation of the back and hip and decreased range of motion. Diagnoses included (paraphrased) right sacroiliitis; right trochanteric bursitis; and left-sided lumbar disc disease. Treatment had included oral and topical analgesics, a muscle relaxant, an NSAID, and massage therapy. The combination therapy is reported to decrease pain by 50% and increase the ability to walk by 15 minutes. A Utilization Review determination was rendered on 06/19/14 recommending non-certification of "Omeprazole 20mg # 120; Hydrocodone/APAP 5/325 Mg #120; and Lido Pro Topical Ointment 4 Oz #2".

IMR ISSUES, DECISIONS AND RATIONALES

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

Lido Pro Topical Ointment 4 Oz #2: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Salicylate Topicals Page(s): 105;111-113;115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain: Topical Analgesics; Salicylate Topicals.

Decision rationale: Lidopro is a compounded agent consisting of menthol, capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methyl salicylate (an anti-inflammatory). 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 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. 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. Therefore, in this case, there is no demonstrated medical necessity for lidocaine as a cream in the compound. 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. 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 request for compounded formulation, Lidopro is not medically necessary.

Hydrocodone/APAP 5/325 Mg #120: 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 Guidelines Functional Improvement Measures; Opioids Page(s): 48;74-83.

Decision rationale: Hydrocodone/APAP is classified as an opioid analgesic in combination with 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 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)." The Guidelines specifically state that opioids are not recommended beyond two weeks. The patient has been on opioids well in excess of 16 weeks. In this case, there is no documentation of the other elements of the pain assessment referenced above or necessity of therapy beyond 16 weeks due to specific functional improvement isolated to this drug. Therefore, there is no documented medical necessity for Hydrocodone with APAP.

Omeprazole 20mg # 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 68-69.

Decision rationale: Prilosec (omeprazole), a proton pump inhibitor, is a gastric antacid. It is sometimes used for prophylaxis against the GI side effects of NSAIDs based upon the patient's risk factors. The Medical Treatment Utilization Schedule (MTUS) notes that these risk factors include (1) age 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAIDs. The use of non-selective NSAIDs without prophylaxis is considered "okay" in patients with no risk factors and no cardiovascular disease. In this case, there is no documentation of any of the above risk factors. Therefore, the medical record does not document the medical necessity for Prilosec.