

Case Number:	CM13-0064893		
Date Assigned:	01/03/2014	Date of Injury:	08/24/2009
Decision Date:	08/01/2014	UR Denial Date:	12/12/2013
Priority:	Standard	Application Received:	12/12/2013

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 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 62 year-old with a date of injury of 08/24/09. A progress report associated with the request for services, dated 11/18/13, identified subjective complaints of neck pain and numbness. Objective findings included decreased range-of-motion of the cervical spine and decreased sensation and motor function of the upper extremities. Diagnoses included herniated disc at C4-5. Treatment had included previous surgery as well as NSAIDs and topical analgesics. A Utilization Review determination was rendered on 12/12/13 recommending non-certification of "Protonix 20mg #60; Voltaren XR 100mg #60; and Terocin lotion 120ml #1".

IMR ISSUES, DECISIONS AND RATIONALES

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

Protonix 20mg #60: Upheld

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: Protonix, 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, the patient was prescribed an NSAID, but there is no documentation of any of the above risk factors. Therefore, the medical record does not document the medical necessity for Protonix.

Voltaren XR 100mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac Sodium (Voltaren, Voltaren XR).

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, Low Back Chapter.

Decision rationale: Voltaren (diclofenac) 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 related to the low back, 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 record indicates that the therapy is long-term rather than for a short period. Since NSAIDs are recommended for the shortest period possible, there must be documented evidence of functional improvement to extend therapy beyond that. In this case, there is no documentation of the functional improvement related to Voltaren and therefore no medical necessity.

Terocin lotion 120ml #1: 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; Topical Salicylates Page(s): 105; 111-113; 115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain: Topical Analgesics; Salicylates Topical.

Decision rationale: Terocin 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) states that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. In this case, there is no demonstrated medical necessity for capsaicin in the compound. 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. In this case, there is recommendation and therefore 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 medical necessity of the compounded formulation, Terocin.