

Case Number:	CM14-0051847		
Date Assigned:	07/07/2014	Date of Injury:	03/23/2011
Decision Date:	09/05/2014	UR Denial Date:	04/01/2014
Priority:	Standard	Application Received:	04/17/2014

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 patient is a 59 year-old with a date of injury of 03/23/11. A progress report associated with the request for services, dated 03/06/14, identified subjective complaints of neck, mid, and low back pain into the right leg. Objective findings included tenderness to palpation of the cervical, thoracic, and lumbar spines. Motor and sensory function was normal with the exception of the left deltoid. Diagnoses included cervical, mid-back, and low back myofascial pain; cervical spondylosis; and possible lumbar spondylosis. Treatment had included oral analgesics and muscle relaxants. A Utilization Review determination was rendered on 04/01/14 recommending non-certification of "Medrox Patch #30; Celebrex 200mg #30; Diclofenac Sodium 3% Gel 100gm #1; Nexium DR 40mg #30 (DOS 3/6/2014)".

IMR ISSUES, DECISIONS AND RATIONALES

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

Medrox Patch #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 Official Disability Guidelines (ODG) Pain: Topical Analgesics; Salicylate Topicals.

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. The request is not medically necessary.

Celebrex 200mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.

Decision rationale: Celebrex is a COX-2 inhibitor non-steroidal anti-inflammatory agent (NSAID). NSAIDs have been 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. Again, no one NSAID was superior to another. 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 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. Additionally, the request is for a COX-2 inhibitor. There was no documentation of underlying ischemic heart disease or gastrointestinal disease. In this case, there is no documentation of the functional improvement related to Celebrex or the need for a COX-2 inhibitor and therefore the request is not medically necessary.

Diclofenac Sodium 3% Gel 100gm #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 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 an 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 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 (low back). Therefore, the medical record does not document the medical necessity for diclofenac topical. The request is not medically necessary.

Nexium DR 40mg #30 (DOS 3/6/2014): Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Proton Pump Inhibitors.

Decision rationale: Nexium (Omeprazole) is a proton pump inhibitor (PPI) antacid. The Medical Treatment Utilization Schedule (MTUS) does not address their use related to medication gastrointestinal side-effects other than with NSAIDs. The Official Disability Guidelines (ODG) notes that PPIs are recommended for patients at risk for gastrointestinal events. It also notes that a trial of omeprazole or lansoprazole is recommended before non-generic Nexium (Omeprazole). In this case, the record does not indicate that the patient has ongoing side-effects from medications. Likewise, that the patient is at risk for a gastrointestinal event. Therefore, the medical record does not document the medical necessity for Nexium (Omeprazole). The request is not medically necessary.