

Case Number:	CM14-0035041		
Date Assigned:	04/09/2014	Date of Injury:	12/13/2012
Decision Date:	05/28/2014	UR Denial Date:	01/25/2014
Priority:	Standard	Application Received:	02/06/2014

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 & 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 60-year-old with a date of injury of 12/13/12. A progress report associated with the request for services, dated 12/20/13, identified subjective complaints of neck, mid, and low back pain. Objective findings included paravertebral spasm and/or tenderness of the lumbar and cervical spines. The diagnoses included axial cervical and lumbar pain and cervical facet arthropathy. The treatment has included oral opioids that she stated made the pain tolerable. A utilization review determination was rendered on 01/31/14 recommending non-certification of "continuance of Norco 5/325 once a day as needed and transdermal compounding creams: Flurbiprofen (20%)/Tramadol (20%), and amitriptyline (10%)/ gabapentin (10%)/dextromethorphan (10%) 240gms."

IMR ISSUES, DECISIONS AND RATIONALES

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

CONTINUANCE OF NORCO 5/325 ONCE A DAY AS NEEDED: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Opioids Page(s): 76-80.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 8 Neck and Upper Back Complaints Page(s): 181; 308, Chronic Pain Treatment Guidelines Section Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Opioids for Chronic Pain.

Decision rationale: Norco 5/325 is a combination drug containing acetaminophen and the opioid hydrocodone. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain 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 state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. The MTUS guidelines note that 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. The Chronic Pain 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." The MTUS Guidelines further state that opioid therapy is not recommended for the neck or low back beyond 2 weeks. The patient has been on Norco in excess of 16 weeks. The Official Disability Guidelines (ODG) state: "While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective achieving the original goals of complete pain relief and functional restoration." In this case, therapy with Norco appears to be ongoing. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. Therefore, the record does not demonstrate medical necessity for Norco.

TRANSDERMAL COMPOUNDING CREAMS: FLURBIPROFEN (20%)/TRAMADOL (20%), AND AMITRIPTYLINE (10%)/GABAPENTIN (10%)/DEXTROMETHORPHAN (10%) ----240GMS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

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, Clinical Journal of Pain. 2008 Jan; 24(1):51-5; www.updates.pain-topics.org; Journal of Anesthesiology. 2010 Oct; 24(5):705-8.

Decision rationale: The requested compound consists of flurbiprofen, a non-steroidal anti-inflammatory drug (NSAID), amitriptyline, a tricyclic antidepressant, gabapentin, an anti-seizure agent, and Tramadol, an opioid analgesic. The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, the MTUS state that topical compounds 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 MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and of short duration. The 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 MTUS 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). The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only Food and Drug Administration (FDA) approved topical NSAID is diclofenac. Neither the MTUS nor the ODG specifically addresses the use of amitriptyline as a topical agent. A randomized, placebo-controlled crossover study examined topical 5% amitriptyline with 5% lidocaine topical in patients with neuropathic pain. The study found that topical amitriptyline was not effective. Therefore, there is no demonstrated medical necessity for topical amitriptyline 10%. Gabapentin 10% is an anti-epilepsy drug. The MTUS Guidelines state that gabapentin is: "Not recommended. There is no peer-reviewed literature to support use." The MTUS further state: "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Tramadol 20% is an opioid analgesic being used as a topical agent. The efficacy of topical Tramadol is not specifically addressed in the MTUS or the ODG. There is some data that topical Tramadol has efficacy directly at an acute postsurgical site. However, there is insufficient data to assure that significant systemic absorption does not occur. 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. As such, the request is not certified.