

Case Number:	CM13-0028219		
Date Assigned:	11/22/2013	Date of Injury:	10/09/2002
Decision Date:	05/19/2014	UR Denial Date:	09/16/2013
Priority:	Standard	Application Received:	09/23/2013

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 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 58 year-old male with a date of injury of 10/9/02. A progress report associated with the request for services, dated 8/6/13, identified subjective complaints of low back pain radiating into the right leg. No gastrointestinal complaints are noted. Objective findings included decreased flexion of the lumbar spine; otherwise, the examination was limited. Diagnoses included lumbar disc disease with radiculopathy. Treatment has included topical and oral medications, including muscle relaxants and opioids for several years. No other therapy is listed. No response or functional improvement related to the therapy is noted. His status is listed as permanent and stationary and included no prolonged standing or walking.

IMR ISSUES, DECISIONS AND RATIONALES

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

90 FLEXERIL 7.5MG: Upheld

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

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

Decision rationale: Flexeril is an antispasmodic muscle relaxant. The MTUS states that muscle relaxants are recommended with caution as a second-line option for the short-term treatment of

acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond non-steroidal anti-inflammatory drug (NSAIDs) in pain and overall improvement. Likewise, the efficacy diminishes over time. The MTUS states specifically that Flexeril is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for Flexeril for chronic use. Though it is noted that Flexeril 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 Flexeril to other agents is not recommended. The record does not give any indications for Flexeril therapy beyond a short course. Likewise, it is being used in combination with other agents. Also, there is no mention of functional improvement related to the medication. Therefore, in this case, the medical record does not document the medical necessity for Flexeril.

30 TRAMADOL 150MG: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Page(s): 74-83, 113. Decision based on Non-MTUS Citation Official Disability Guidelines

Decision rationale: Tramadol is a centrally acting synthetic opioid analgesic. The California 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. 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 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. Opioids are not recommended for more than two weeks and the guidelines further state that Tramadol is not recommended as a first-line oral analgesic. This patient has been on Tramadol in excess of 16 weeks. 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.

90 PRILOSEC 20MG: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

Decision rationale: Prilosec is a proton pump inhibitor (PPI) antacid. The 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 (esomeprazole). The record does not indicate that the patient has ongoing side-effects from medications and is not taking concurrent NSAIDs. Therefore, the medical record does not document the medical necessity for Prilosec (Omeprazole).

KETOPROFEN, GABAPENTIN, AND TRAMADOL TOPICAL CREAMS: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines; and www.updates.pain-topics.org; J Anesth. 2010 Oct;24(5):705-8.

Decision rationale: The requested compound consists of Gabapentin, an anti-seizure agent; Ketoprofen, an NSAID being used as a topical analgesic; and Tramadol, a centrally acting opioid analgesic. The MTUS Chronic Pain Medical Treatment 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 MTUS guidelines state that Gabapentin is not recommended as there is no peer-reviewed literature to support its use. Therefore, there is no documented medical necessity for the addition of Gabapentin in the topical formulation for this patient. The efficacy of topical NSAIDs (like Ketoprofen) in osteoarthritis has been inconsistent. 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. The only FDA approved topical NSAID is Diclofenac. Ketoprofen is not approved and has an extremely high incidence of photocontact dermatitis and photosensitization reactions. The efficacy of topical Tramadol is not specifically addressed in the MTUS or the Official Disability Guidelines (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. Lacking definitive data on the efficacy of topical Tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy. Therefore, medical necessity for topical Tramadol has not been established. The guidelines further state that 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. As such, the request is not medically necessary.