MAXIMUS Federal Services

| Case Number: | CM13-0044833 | | |
|---|---|---|---|
| Date Assigned: | 03/21/2014 | Date of Injury: | 05/20/2012 |
| Decision Date: | 05/23/2014 | UR Denial Date: | 10/23/2013 |
| Priority: | Standard | Application Received: | 10/29/2013 |

## 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:

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. 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. 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 (> 16 weeks) is unclear, 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. Therefore, the record does not document the medical necessity for Tramadol.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**60 TRAMADOL ER 150MG (RETROSPECTIVE: 9/20/13):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308,Chronic Pain Treatment Guidelines Page(s): 74-96, 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. 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. 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 (> 16 weeks) is unclear, 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. Therefore, the record does not document the medical necessity for Tramadol.

**90 NAPROXEN SODIUM 550MG (RETROSPECTIVE 9/20/13):** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 12, 67-73;. Decision based on Non-MTUS Citation Official Disability Guidelines

**Decision rationale:** Naproxen is a non-steroidal anti-inflammatory agent (NSAID). The MTUS states that NSAIDs are recommended for use in osteoarthritis. It is noted also that they are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. 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 non-certification was based upon lack of recommended use of NSAIDs for chronic pain control. However, the MTUS states that acetaminophen and NSAIDs are both recommended as first-line therapy for chronic low back pain. The non-certification was based upon lack of documentation for subjective or objective improvement with naproxen. However, there is documentation of chronic low back and peripheral joint pain that is in-part controlled by naproxen. Additionally, there is documentation that the medication improves function. Therefore, the record does document the medical necessity for naproxen.

**90 PANTOPRAZOLE 20MG (RETROSPECTIVE: 9/20/13):** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** Pantoprazole, 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 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 non-certification was based upon lack of documentation for complaints of gastritis or need for prophylaxis. However, there is documentation of NSAID-induced GI upset that has been controlled with pantoprazole. Therefore, the medical record does document the medical necessity for pantoprazole.

**90 CYCLOBENZAPRINE 7.5MG:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** Cyclobenzaprine is an antispasmodic muscle relaxant. The MTUS states that muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The MTUS states that Cyclobenzaprine is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for Cyclobenzaprine for chronic use. Though it is noted that Cyclobenzaprine 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 Cyclobenzaprine to other agents is not recommended. The guidelines do note that Cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. The record does not show any evidence of fibromyalgia, and other indications for Cyclobenzaprine beyond a short course are not well supported. Likewise, it is being used in combination with other agents, particularly NSAIDs for which no additional benefit has been shown. Therefore, in this case, the medical record does not document the medical necessity for Cyclobenzaprine.