

Case Number:	CM14-0165547		
Date Assigned:	10/10/2014	Date of Injury:	10/18/2013
Decision Date:	12/31/2014	UR Denial Date:	09/08/2014
Priority:	Standard	Application Received:	10/07/2014

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 Emergency Medicine and is licensed to practice in New York. 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:

The patient is a 49-year-old male who was injured on October 18, 2013. The patient continued to experience pain in his right ankle. Physical examination was notable for decreased range of motion of the right ankle and normal muscle strength of the right lower extremity. Diagnoses included sprain right ankle and degenerative arthritis right ankle. Treatment included medications and ankle brace. Requests for authorization for Flurbiprofen/Lansoprazole 100/10 mg #60, Tramadol/Acetaminophen/Ondansetron 50/250/2 #90, and Flurbiprofen/Lidocaine cream 180 gm were submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Lansoprazole 100mg/10mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; Anti-inflammatory.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 67-68.

Decision rationale: This is a compounded medication containing Flurbiprofen and Lansoprazole. Flurbiprofen is a nonsteroidal anti-inflammatory drug (NSAID), recommended for the treatment of osteoarthritis and mild to moderated pain. Chronic Medical Treatment

Guidelines state that "anti-inflammatory drugs are the traditional first line of treatment, but long term use may not be warranted". For osteoarthritis it was recommended that the lowest dose for the shortest length of time be used. It was not shown to be more effective than acetaminophen, and had more adverse side effects. Adverse effects for GI toxicity and renal function have been reported. Medications for chronic pain usually provide temporary relief. Medications should be prescribed only one at a time and should show effect within 1-3 days. Record of pain and function with the medication should be documented. In this case, there is no documentation of the duration or efficacy of treatment with the Flurbiprofen. The quantity of medication requested indicates long-term use. The duration of treatment increases the risk of adverse effects with little benefit. Flurbiprofen is not recommended. Lansoprazole is a proton pump inhibitor (PPI). PPIs are used in the treatment of peptic ulcer disease and may be prescribed in patients who are using non-steroidal anti-inflammatory drugs and are at high risk for gastrointestinal events. Risk factors for high-risk events are age greater than 65, history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). The patient in this case was using NSAID medication, but did not have any of the risk factors for a gastrointestinal event. It is not recommended. The guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains drugs that are not recommended. Therefore, this request is not medically necessary.

Tramadol/Acetaminophen/Ondansetron 50/250/2mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; Anti-inflammatory.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 11, 74-96. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Pain: Antiemetics (for opioid nausea)

Decision rationale: This is a compounded medication containing Tramadol, Acetaminophen, and Ondansetron. Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDs have failed. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. In this case, there is no documentation regarding the duration or efficacy of treatment with Tramadol. The quantity of medication requested indicates long-term use. There is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. Criteria for long-term opioid use have not been met. Tramadol is not recommended. Acetaminophen is recommended for

treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. Ondansetron, a serotonin 5-HT₃ receptor antagonist, is an antiemetic. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. Antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. Ondansetron is not recommended. The guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains drugs that are not recommended. Therefore, this request is not medically necessary.

Flurbiprofen/Lidocaine 20%/5% cream 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; Anti-inflammatory.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112.

Decision rationale: This medication is a topical analgesic containing Flurbiprofen and Lidocaine. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Flurbiprofen is recommended as an oral agent for the treatment of osteoarthritis and the treatment of mild to moderate pain. It is not recommended as a topical preparation. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy, such as an antidepressant or antiepileptic drug. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. In this case, there is no documentation that the patient has failed treatment with anticonvulsants or antidepressants. Lidocaine is not recommended. This medication contains drugs that are not recommended. Therefore, this request is not medically necessary.