

Case Number:	CM14-0132880		
Date Assigned:	08/22/2014	Date of Injury:	10/11/2013
Decision Date:	12/31/2014	UR Denial Date:	07/18/2014
Priority:	Standard	Application Received:	08/18/2014

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 46-year-old male who was injured on October 11, 2013. The patient continued to experience lower back pain. Physical examination was notable for normal muscle tone, positive right straight leg raise, and decreased sensation to light touch on right L4, L5 and S1 distributions. Diagnoses included musculoligamentous sprain lumbar spine with lower extremity radiculitis, musculoligamentous sprain of thoracic spine and multilevel lumbar disc bulge. Treatment included medications, Requests for authorization for hydrocodone/ APAP/ ondansetron 10/300/2 mg #30, ondansetron 2 mg, flurbiprofen/ranitidine 100/100 mg #90, flurbiprofen/lidocaine cream 180 gm, and orphenadrine 100 mg #60 were submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hydrocodone/APAP/Ondansetron 10/300/2mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain: Antiemetics (for opioid nausea).

Decision rationale: This medication is a compounded medication containing hydrocodone, acetaminophen, and ondansetron. Hydrocodone is an opioid medication. 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 of 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 the patient is already taking Norco, which contains hydrocodone and acetaminophen. There is no documentation with regards to the duration or efficacy of hydrocodone. In addition there is no documentation of a signed opioid contract or participation in urine drug testing. Hydrocodone 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 a gastrointestinal event. 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 the request is not medically necessary.

Ondansetron 2mg (no quantity given): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary.

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

Decision rationale: 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 a gastrointestinal event. Medical necessity has not been established. Therefore, the request is not medically necessary.

Flurbiprofen/ Ranitidine 100/100mg #90 3refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 67-68. Decision based on Non-MTUS Citation The Medical Letter on Drugs and Therapeutics; March 8, 2010 (Issue 1333) page 17: Primary Prevention of Ulcers in Patients Taking Aspirin or NSAIDs.

Decision rationale: This medication is a compounded medication containing flurbiprofen and ranitidine. 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. 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 the requested quantity of medication indicates long-term use. The patient has not obtained analgesia. The duration of use increases the risk of adverse effects without benefits. The medication is not recommended. Ranitidine is an H2-receptor antagonist. It is indicated for the treatment of peptic ulcer disease and been shown to prevent NSAID-related gastric ulcers in high doses. In this case the patient did not have diagnosis of ulcer disease. The patient did not have any complaint of nausea or dyspepsia. 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 the medication cannot be recommended. The request is not medically necessary.

Flurbiprofen/Lidocaine Cream 20%/5% #180gm 3refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Lidoderm Â® (lidocaine patch).

Decision rationale: This 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 tried and failed treatment with antidepressants or anticonvulsants. Lidocaine is not recommended. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

Orphenadrine 100mg #60 3refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63, 65.

Decision rationale: Orphenadrine is a muscle relaxant. Orphenadrine is similar to diphenhydramine, but has greater anticholinergic effects. Effects are thought to be secondary to analgesic and anticholinergic properties. Side effects are primarily anticholinergic and include drowsiness, urinary retention, and dry mouth. Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. Non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment (less than two weeks) of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. In this case the quantity of medication indicates use for at least 120 days. The duration of treatment surpasses the recommended short-term duration of two weeks. The request is not medically necessary.