

Case Number:	CM13-0006776		
Date Assigned:	07/02/2014	Date of Injury:	02/11/2011
Decision Date:	08/05/2014	UR Denial Date:	07/24/2013
Priority:	Standard	Application Received:	08/05/2013

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 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 42-year-old male who was injured on February 22, 2011. The patient continued to experience pain in his neck with radiation into his left arm. Physical examination was notable for normal motor strength of the bilateral upper extremities, intact sensation to the bilateral upper extremities, and painful range of motion to the cervical spine. Diagnoses included cervical post laminectomy syndrome and cervical spondylosis. Treatment included surgery, physical therapy, medications, and stretching exercises. Requests for authorization for Zanaflex 4 mg comfort kit, Ultram 50 mg, Vicoprofen 220 mg/7.5 mg, and Prilosec 20 mg were submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zanaflex 4mg Comfort Kit (Zanaflex 4mg and Duraflex Cream): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63, 65, 111-112.

Decision rationale: Zanaflex kit contains Tizanidine and Duraflex cream. Tizanidine is a muscle relaxant that acts centrally as an alpha2-adrenergic agonist that is FDA approved for management of spasticity. Side effects include somnolence, dizziness, dry mouth, hypotension,

weakness, and hepatotoxicity. 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 Zanaflex kit was ordered with a 30 day supply with 3 refills. The anticipated duration of treatment surpasses the short term duration of less than two weeks. The medication is not recommended. Duraflex cream is topical methyl salicylate. Methyl salicylate is a topical salicylate and is recommended, being significantly better than placebo in chronic pain. This medication kit contains a medication that is not recommended. The medication is, therefore, not recommended. Therefore, the request for Zanaflex 4mg Comfort Kit (Zanaflex 4mg and Duraflex Cream) is not medically necessary and appropriate.

Ultram 50mg: 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 rationale: Ultram is 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 (Selective Serotonin Reuptake Inhibitors), 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. In this case the medication was not prescribed for short term use and the criteria for opioid use were not met. In this case the medication was prescribed for 30 days with 4 refills. The duration meets the definition of long-term use. There is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. In addition the patient has not obtained analgesia. Criteria for long-term use have not been met. Therefore, the request for Ultram 50mg is not medically necessary and appropriate.

Vicoprofen 220mg/7.5 mg: 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): 67-68, 74-96.

Decision rationale: Vicoprofen is the compounded medication containing hydrocodone and ibuprofen. 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 medication was not prescribed for short-term use and the criteria for opioid use were not met. In this case the medication was prescribed for 30 days with 4 refills. The duration meets the definition of long-term use. There is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. In addition the patient has not obtained analgesia. Criteria for long-term use have not been met. The medication is not recommended. Ibuprofen is a non-steroidal anti-inflammatory drug. Chronic Medical Treatment Guidelines state that "anti-inflammatory drugs are the traditional first line of treatment, but long term use may not be warranted". NSAID's have not been shown to be more effective than acetaminophen, and have more adverse side effects. Adverse effects for GI toxicity and renal function have been reported. In this case the medication was prescribed for 30 days with 4 refills. The duration of treatment surpasses the recommended short-term use. It is not recommended. This compounded medication contains medications that are not recommended. The Vicoprofen is, therefore, not recommended. Therefore, the request for Vicoprofen 220mg/7.5 mg is not medically necessary and appropriate.

Prilosec 20 Mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

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

Decision rationale: Prilosec is omeprazole, a proton pump inhibitor (PPI). PPI's 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 (non-steroidal anti-inflammatory drugs) (e.g., NSAID + low-dose Acetyl salicylic Acid). The patient

in this case was using NSAID medication, but did not have any of the risk factors for a gastrointestinal event. As such, the request for Prilosec 20 Mg is not medically necessary and appropriate.