

Case Number:	CM13-0024673		
Date Assigned:	11/20/2013	Date of Injury:	10/09/2008
Decision Date:	01/16/2014	UR Denial Date:	09/04/2013
Priority:	Standard	Application Received:	09/16/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation and is licensed to practice in California, Florida and Maryland. 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 physician 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 claimant is a 39 year old male with a date of injury of 10/9/2008 and was diagnosed with generalized pain, thoracic sprain/strain, lumbar sprain/strain, and cervical sprain/strain. He was considered permanent and stationary as of 4/25/2012, and his work status as of 12/2012 indicated he was at regular work. A previous EMG/NCV study reported he was positive for slowing nerve conduction across the elbow at the cubital tunnel. Furthermore, the patient was status post (11/03/2008) right clavicle open reduction with internal fixation (ORIF), with a co-morbidity of hypertension and chronic right shoulder, neck, upper back, headaches and low back complaints. The provider submitted retrospective requests for 120 Naproxen Sodium 550mg, 120 Cyclobenzaprine Hydrochloride 7.5mg, 120 Omeprazole DR 20mg, 30 Medrox Patch, and 90 Tramadol ER 150mg dispensed on 7/25/2013, which was the subject of this review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine Hydrochloride 7.5mg #120: 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 Antispasmodics Page(s): 64.

Decision rationale: According to Chronic Pain Medical Treatment Guidelines MTUS (Effective July 18, 2009), Antispasmodics which includes Flexeril also known as Cyclobenzaprine, is used to decrease muscle spasm in conditions such as LBP although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. (Chou, 2004). They are recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004). The recommended dosage is 5-10mg thrice daily, for not longer than 2-3 weeks, with the greatest benefit in the first 4 days of therapy. Therefore 120 tablets of Cyclobenzaprine Hydrochloride 7.5 mg is not medically necessary.

Omeprazole DR 20mg #120: 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 NSAID Therapy Page(s): 68 and 127.

Decision rationale: Omeprazole is a proton-pump inhibitor (PPI) which can be used as a co-treatment of patients on NSAID therapy who at risk of gastro-intestinal bleeding. CA-MTUS (Effective July 18 2009) Guidelines recommend determining first the risk factors for gastrointestinal events and cardiovascular disease. When a patient is at a low risk for gastrointestinal event and cardiovascular disease, a full-dose naproxen is the preferred choice of NSAID medication. If and when naproxen is ineffective, the addition of an aspirin and a PPI is an option. A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 \hat{I} ¼g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). According to medical records, the patient did not have a history of gastrointestinal issues, and additionally, the patient was not concurrently prescribed aspirin, corticosteroids, anticoagulants, or a high dose of NSAIDs that have caused an adverse reaction in the past. Taking into consideration the above discussion, the retrospective request for 120 Omeprazole DR 20mg is not medically necessary.

The request for thirty (30) Medrox patches: 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 Topical Analgesics Page(s): 112 to 113.

Decision rationale: According to MTUS, the use of topical analgesics is largely experimental with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, $\hat{1}\pm$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, $\hat{1}\beta$ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The Compound Medrox is a mixture of methyl salicylate, menthol, capsaicin prescribed as a patch for neuropathic pain management. Although MTUS (July 18, 2009) Chronic Pain Medical Treatment Guidelines page 112 to 113, made no mention of Menthol as a recommended topical analgesic, however literature search of Journal of Pharmacology and Experimental Therapeutics Published on September 5, 2012 revealed that Menthol is one of the most commonly used chemicals in our daily life, not only because of its fresh flavor and cooling feeling but also because of its medical benefit. Previous studies have suggested that menthol produces analgesic action in acute and neuropathic pain through peripheral mechanisms. However, the central actions and mechanisms of menthol remain unclear. Recent studies report that menthol has direct effects on the spinal cord. Menthol decreased both ipsilateral and contralateral pain hypersensitivity induced by complete Freund's adjuvant in a dose dependent manner. Menthol also reduced both first and second phases of formalin-induced spontaneous nocifensive behavior. CA-MTUS primarily recommended topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no documentation that this is the case, therefore the prescription of 30 Medrox patch is not medically necessary.

Tramadol ER 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75, 80 and 84.

Decision rationale: MTUS (Effective July 18, 2009) Chronic Pain Medical Treatment Guidelines (pages 75, 80 and 84), Tramadol (Ultram) - classified as a small class of synthetic opioids, with opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine as a Central acting analgesics. This class of synthetic opioids have been reported to be effective in managing neuropathic pain, with side effects similar to traditional opioids. "Opioids efficacy is limited to short term pain relief, and long term efficacy is unclear". Failure to respond to a time-limited course of opioids has led to suggestion of reassessment and consideration of alternative therapy. A recent Cochrane review found that Ultram decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline). Adverse events often caused study participants to discontinue this medication, and could limit usefulness. Absent and indications of flare-ups of the patient's pain complaints, the prescription of 90 tablets of Ultram 50mg is not medically necessary.â€