

<b>Case Number:</b>	CM13-0022366		
<b>Date Assigned:</b>	11/13/2013	<b>Date of Injury:</b>	07/16/2012
<b>Decision Date:</b>	01/13/2014	<b>UR Denial Date:</b>	08/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/10/2013

### 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 Internal Medicine, has a subspecialty in Pulmonary Disease and is licensed to practice in California. 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:

This patient is a 46-year-old female who reported an injury on 07/16/2012. The documentation submitted for review indicates the mechanism of injury is continuous trauma. The most recent clinical notes detailing an examination of the patient are from 07/17/2013. The notes indicate the patient has persistent pain to the neck aggravated by repetitive motion of the neck and prolonged positioning of the neck, as well as with pushing, pulling, lifting, forward reaching, and working at or above shoulder level. The patient also has complaints of low back pain that is aggravated by bending, lifting, twisting, pulling, sitting, standing, and walking multiple blocks. The patient also has pain of the bilateral upper extremities which remains unchanged. The notes indicate the patient has been prescribed medications to include naproxen 550 mg, cyclobenzaprine 7.5 mg, sumatriptan 25 mg, ondansetron ODT tablets 8 mg, omeprazole delayed release capsule 20 mg, and Medrox relief ointment.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**The naproxen sodium 550mg #100 dispensed on 8/14/13.: 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 Anti-inflammatory Medications Page(s): 22.

**Decision rationale:** CA MTUS states that anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic low back pain (LBP) and of antidepressants in chronic LBP. While the documentation submitted for review indicates the patient to have complaints of cervical and lumbar spine pain, bilateral lower extremities pain, and bilateral upper extremities pain, there is lack of documentation submitted for review detailing the efficacy of this medication in treatment of the patient's pain. Furthermore, guidelines indicate this medication is indicated as a traditional first-line treatment to reduce pain so activity and functional restoration can resume; however, there is no indicated improvement of the patient. The request for naproxen sodium is not medically necessary and appropriate.

**The cyclobenzaprine 7.5mg #120 dispensed on 8/14/13.: 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 Cyclobenzaprine Page(s): 41.

**Decision rationale:** CA MTUS states that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. Flexeril is more effective than placebo in the management of back pain; however, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Therefore, treatment should be brief. However, the documentation submitted for review indicates the patient has been prescribed cyclobenzaprine 7.5 mg since at least 02/13/2013. Further treatment with the medication exceeds recommendation of the guidelines for brief treatment with cyclobenzaprine. The request for cyclobenzaprine is not medically necessary and appropriate.

**The sumatriptan succinate 25mg #18 dispensed on 8/14/13.: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Side effects of Imitrex (Sumatriptan Succinate), from Rxlist.com..

**Decision rationale:** CA MTUS/ACOEM Guidelines does not address Sumatriptan. The Official Disability Guidelines do not address Sumatriptan. Clinical literature indicates that Sumatriptan is a synthetic drug belonging to the triptan class, and is used for the treatment of migraine headaches. Imitrex is available as a generic drug and is used in oral, intranasal or injectable. While the documentation submitted for review indicates the patient to have pain to the cervical

spine, bilateral upper extremities, lumbar spine, and bilateral lower extremities, there is lack of documentation indicating the patient currently suffers migraine headaches to support the recommendation of this medication. The request for sumatriptan succinate is not medically

**Ondansetron ODT 4mg.:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Ondansetron: MedlinePlus Drug Information" on [www.nlm.nih.gov](http://www.nlm.nih.gov)..

**Decision rationale:** CA MTUS/ACOEM Guidelines do not address Ondansetron. The Official Disability Guidelines do not address Ondansetron. Clinical literature states that Ondansetron (Zofran) is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy, and surgery. Ondansetron is in a class of medications called serotonin 5-HT<sub>3</sub> receptor antagonists. It works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting. However, there is lack of documentation indicating the patient currently suffers with nausea. Furthermore, there is lack of documentation indicating the necessity for prescription of Zofran, as well as a proton pump inhibitor concurrently. The request for ondansetron is not medically necessary and appropriate.

**Omeprazole 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 NSAIDs & GI symptoms Page(s): 68.

**Decision rationale:** CA MTUS states that patients at intermediate risk for gastrointestinal events and no cardiovascular disease should consider use of a non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily or a medication such as misoprostol (200  $\hat{I}$ ¼g four times daily); or use of a Cox-2 selective agent. Caution is given with long-term use of proton pump inhibitors as studies of use of PPI's show that use for (> 1 year) has increased the risk of hip fracture. However, there is lack of documentation submitted for review indicating a clear clinical rationale for the necessity of the prescription of omeprazole 20 mg, as well as ondansetron ODT 4 mg concurrently. Also, there is lack of documentation indicating current GI symptoms of the patient or to indicate prior history of gastrointestinal bleeding, ulcers, or gastroesophageal reflux disease. The request for omeprazole is not medically necessary and appropriate.

**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 Page(s): 105,111,113. Decision based on Non-MTUS Citation article on Medrox patches on [www.dailymed.nlm.nih.gov](http://www.dailymed.nlm.nih.gov).

**Decision rationale:** CA MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety; also, that they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Many agents are compounded as monotherapy or in combination for pain control; however, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, therefore, is not recommended. 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. CA MTUS states that salicylate topicals are recommended as significantly better than placebo in chronic pain. CA MTUS states Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations of Capsaicin are generally available as a 0.025% formulation and a 0.075% formulation. However, there have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. While there is support in the guidelines for methyl salicylate topicals, the current peer-reviewed literature indicates Medrox contains capsaicin at a formulation of 0.0375% and per the guidelines, there is lack of clinical study indicating that a 0.0375% formulation of capsaicin provides any further efficacy over a 0.025% formulation. The request for Medrox patches is not medically necessary and appropriate.

**Tramadol ER 150mg #90.: 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): 82,93,94.

**Decision rationale:** CA MTUS states opioid analgesics and tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). Tramadol is a synthetic opioid affecting the central nervous system and may increase the risk of seizure especially in patients taking SSRIs, TCAs and other opioids. Tramadol should not be prescribed to patients that at risk for suicide or addiction. CA MTUS also states a recommendation for the 4 A's for Ongoing Monitoring. These four domains for monitoring have been summarized as the "4 A's" and include monitoring for include analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) While the documentation submitted for review indicates the

patient has suffered from cervical spine and lumbar spine pain, as well as bilateral upper extremities and bilateral lower extremities pain due to repetitive motion, there is lack of documentation submitted for review indicating effective analgesia with tramadol or to indicate an improvement in the patient's ability to undertake activities of daily living or to indicate that aberrant drug related behaviors or if any adverse side effects of the medications exist and have been addressed. The request for tramadol ER is not medically necessary and appropriate.