

<b>Case Number:</b>	CM13-0019250		
<b>Date Assigned:</b>	10/11/2013	<b>Date of Injury:</b>	10/18/2009
<b>Decision Date:</b>	01/27/2014	<b>UR Denial Date:</b>	08/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/03/2013

### 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. 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:

45 year old male with an Oct 18 2009 injury involving Cervical and Thoracic spine, diagnosed with Cervical discopathy: bilateral carpal tunnel syndrome, right cubital tunnel syndrome and right guyon canal syndrome & Lumbar discopathy. Previous therapies were epidural steroid injection, physical therapy, acupuncture and chiropractic treatment. Retrospective of Omeprazole, Cyclobenzaprine and Tramadol were denied, thus this appeal process. According to the orthopedic progress report submitted by [REDACTED] dated 7/22/12, the patient complained of occasional flare-up of low back pain with stiffness, accompanied by occasional radiating pain. He already had one lumbar epidural injection with significant improvement. However, pain recurred. The cervical symptomatology remained unchanged with migrainous headaches associated with periods of increased cervical pain. The headaches caused nausea which was not alleviated with Prilosec. The patient reported compliance with previously provided medications but experienced upset stomach with Naproxen use. He continued the use of Naproxen since it provided temporary pain relief and facilitated the performance of his activities of daily living. The objective findings included cervicalparavertebral muscles tenderness and pain with terminal motion, mid to distal lumbar segmentstenderness with terminal motion pain, and positive seated nerve root test. He was diagnosed with cervicdiscopathy; incidental findings of bilateral carpal tunnel syndrome; right cubital tunnel syndrome andright Guyon canal syndrome; and lumbar discopathy. The patient was to continue his full duty work.Review of the available reports indicated that previous treatment protocol included medications, anepidural steroid injection, physical therapy, acupuncture, and chiropractic treatment.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Omeprazole DR 20mg #120 for DOS 5/9/2013: 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): 67.

**Decision rationale:** According to Chronic Pain Medical treatment Guidelines MTUS (effective July 18, 2009), page 68 of 127, patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 µg four times daily) or (2) a Cox-2 selective agent is recommended. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44) Regarding the request for Omeprazole,, prophylactic use of this medication is not recommended for patients without any risk factors. Other than a history of upset stomach, after taking naproxen reported by the patient, the physician diagnosis list did not include gastritis, therefore the request for Omeprazole 20mg # 120 is not medically necessary.

**Retrospective Cyclobenzaprine 7.5mg #120 for DOS 5/9/2013: 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), page 64, Anti-Spasmodics 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 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. Although the patient complained of occasional flare-up of pain and symptoms which remained mostly unchanged. The guidelines only recommended a short course of muscle relaxants after a failed trial of NSAIDs for pain during acute exacerbation of symptoms. There was no documented report of recent NSAIDs failed trial for this recent flare-up, therefore the retrospective Cyclobenzaprine 7.5mg #120 for DOS 5/9/2013 is not medically necessary.

**Retrospective Tramadol ER 150mg #90 for DOS 5/9/2013: 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 Opioids Page(s): 75, 80 & 84.

**Decision rationale:** CA-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 patients pain complaints, the prescription of 90 tablets of Ultram ER 150mg is not medically necessary.

**Retrospective request for two (2) prescriptions of Medrox pain relief ointment 120gm for DOS 5/9/2013: 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): 111-113.

**Decision rationale:** According to CA-MTUS (Effective July 18, 2009) page 111 of 127, section on Topical Analgesics- 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. The guideline 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 Medrol patch is not medically necessary. Therefore the request for retrospective request for two (2) prescriptions of Medrox pain relief ointment 120gm for DOS 5/9/2013)