

<b>Case Number:</b>	CM13-0023737		
<b>Date Assigned:</b>	12/11/2013	<b>Date of Injury:</b>	04/26/2001
<b>Decision Date:</b>	01/23/2014	<b>UR Denial Date:</b>	09/06/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/13/2013

### 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:

The patient is a 49 year old female who sustained a work injury on April 26, 2001. She is diagnosed with chronic pain syndrome, status post lumbar fusion L4-5, LS-S1, and degenerative disc disease of the cervical, thoracic, and lumbar spine. She reports persistent neck and back pain, which she rates at 9/10 on pain scale. She notes bilateral upper and lower extremity numbness, tingling, and burning. Physical examination is significant for antalgic gait; range of motion of the cervical and lumbar spines is decreased in all planes. There is decreased sensation on the left C6, C7, and C8 dermatomes, and decreased sensation on the left L5 and S1 dermatomes. Upper extremity and lower extremity motor exam is limited by pain, there is positive facet loading bilaterally in the cervical spine. She is status post cervical facet medial branch block at Left C4-5, C5-6, and C6-7 facets. She also has had water therapy and various medications. She states that the medications and therapies have helped decrease her pain and increased her activity level. At issue is whether 1). Medrox Patches box #4, 2). Omeprazole 20 mg #120, 3). Zanaflex 4 mg #180, 4). Celebrex samples 200 mg #7, 5). Trigger Point Injections into the right lumbar paravertebral musculature, and 6). Trigger Point Injections into the left lumbar paravertebral musculature are medically necessary.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**(4) boxes of Medrox Patches:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 113. Decision based on Non-MTUS Citation Journal of Pharmacology and Experimental Therapeutics (JPET Fast Forward. Published on September 5, 2012 as DOI:10.1124/jpet.112.196717).

**Decision rationale:** The Compund Medrox is a mixture of methyl salicylate, menthol, capsaicin prescribed as a patch for neuropathic pain management. Although the Chronic Pain Medical Treatment Guidelines, 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 remains 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. Therefore the request for four (4) boxes of Medrox Patches is medically necessary and appropriate.

**120 tablets of Omeprazole 20mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Portion Pump Inhibitors (PPIs)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines recommends clinicians to determine the risk for gastrointestinal events. Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastro-duodenal lesions. In 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. In patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. The patient has documented gastrointestinal symptoms, and is on a Cox-2 selective agent, Celebrex, thus Omeprazole use is indicated for gastrointestinal protection. However, the patient is prescribed Omeperazole 20mg #120, while the recommended dose is Omeprazole 20 mg once daily #30. Therefore, Omeprazole 20mg #120 is not medically necessary.

**180 tablets of Zanaflex 4mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity Antispasmodic Drugs. Page(s): 66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine Page(s): 66.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines states that Tizanidine (Zanaflex®) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. Eight studies have demonstrated efficacy for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. It may also provide benefit as an adjunct treatment for fibromyalgia. It is recommended to use this medication with caution in renal impairment; should be avoided in hepatic impairment. Tizanidine use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with Discontinuation. Beside being unlabelled for low back pain treatment, there is no documentation of this patients renal or hepatic function test result in the record reviewed, prior to prescription of this medication. Therefore the request for Tizanidine 4mg #180 is not medically necessary

**retrospective request for seven (7) Celebrex 200mg (Dispensed: 8/6/2013):** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), Page 67-73. Page(s).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 22,23.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines states that Celebrex® is the brandname for celecoxib. Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. Unlike other NSAIDs, celecoxib does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures. COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Antiinflammatories 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. Therefore the request for Celebrex 20mg #7 is medically necessary.

**retrospective request for one (1) Trigger Point Injections into the right lumbar paravertebral musculature (DOS:8/6/2013):** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Trigger Point Injections Page(s): 122.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Trigger Point Injections Page(s): 122.

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines Trigger Point Injection is recommended only for myofascial pain syndrome with limited lasting value. Trigger point injections with a local anesthetic may be recommended for the treatment of chronic low back or neck pain with myofascial pain syndrome when all of the following criteria are met: (1) Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain; (2) Symptoms have persisted for more than three months; (3) Medical management therapies such as ongoing stretching exercises, physical therapy, NSAIDs and muscle relaxants have failed to control pain; (4) Radiculopathy is not present (by exam, imaging, or neuro-testing); (5) Not more than 3-4 injections per session; (6) No repeat injections unless a greater than 50% pain relief is obtained for six weeks after an injection and there is documented evidence of functional improvement; (7) Frequency should not be at an interval less than two months; (8) Trigger point injections with any substance (e.g., saline or glucose) other than local anesthetic with or without steroid are not recommended. This patient has a diagnosis of myofascial pain syndrome, therefore the retrospective request for one (1) Trigger Point Injections into right lumbar paravertebral musculature (DOS:8/6/2013) is medically necessary.

**retrospective request for one (1) Trigger Point Injections into the left lumbar paravertebral musculature (DOS:8/6/2013):**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Trigger Point Injections Page(s): 122.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Trigger Point Injections Page(s): 122.

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines Trigger Point Injection is recommended only for myofascial pain syndrome with limited lasting value. Trigger point injections with a local anesthetic may be recommended for the treatment of chronic low back or neck pain with myofascial pain syndrome when all of the following criteria are met: (1) Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain; (2) Symptoms have persisted for more than three months; (3) Medical management therapies such as ongoing stretching exercises, physical therapy, NSAIDs and muscle relaxants have failed to control pain; (4) Radiculopathy is not present (by exam, imaging, or neuro-testing); (5) Not more than 3-4 injections per session; (6) No repeat injections unless a greater than 50% pain relief is obtained for six weeks after an injection and there is documented evidence of functional improvement; (7) Frequency should not be at an interval less than two months; (8) Trigger point injections with any substance (e.g., saline or glucose) other than local anesthetic with or without steroid are not recommended. This patient has a diagnosis of myofascial pain syndrome, therefore the retrospective request for one (1) Trigger Point Injections into left lumbar paravertebral musculature (DOS:8/6/2013) is medically necessary.

