

<b>Case Number:</b>	CM13-0045890		
<b>Date Assigned:</b>	12/27/2013	<b>Date of Injury:</b>	12/05/2012
<b>Decision Date:</b>	03/11/2014	<b>UR Denial Date:</b>	10/25/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/12/2013

### 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 Orthopedic Surgery, 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:

47 year old male with date of injury 12/5/12 with complaint of foot pain. Exam note from 9/17/13 demonstrates left foot pain consistent with left plantar fasciitis. Exam note 9/30/13 demonstrates left foot tenderness at the left plantar fasciitis. Reports foot specialist recommended physical therapy and orthotics. Exam note 7/30/13 demonstrates tenderness over bilateral plantar aspect of feet. Exam note 7/16/13 demonstrates left foot tenderness over plantar aspect. Report of patient with limp favoring left side.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Naproxen Sodium 550 mg, #100:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Low back pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**Decision rationale:** Per the MTUS guidelines, Naproxen is a nonsteroidal anti-inflammatory drug (NSAID) for the relief of the signs and symptoms of osteoarthritis. Per ODG, for acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients

with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. There is no evidence in the medical records of supporting osteoarthritis or failure of acetaminophen to support medical necessity. Therefore determination is non-certification.

**Cyclobenzaprine Hcl 7.5 mg, #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.

**Decision rationale:** According to the CA MTUS Chronic Pain Medical Treatment Guidelines, Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) 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. (Homik, 2004) 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. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, Cyclobenzaprine, Metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008) Specifically with regards to Flexeril, the CA MTUS Chronic Pain Medical Treatment Guidelines state, "Recommended as an option, using a short course of therapy. Cyclobenzaprine (Flexeril®) is more effective than placebo in the management of back pain; 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. (Browning, 2001) Treatment should be brief. There is also a post-op use. The addition of Cyclobenzaprine to other agents is not recommended." In this particular case the patient has no evidence of low back pain to warrant use. Therefore is not medically necessary and non-certified.

**Omeprazole caps 20 mg, #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.

**Decision rationale:** Per the CA MTUS regarding Prilosec Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) 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  $\hat{I}$ 4g 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. In this case there is lack of medical necessity in the records that the claimant has no medical evidence suggesting increased risk for gastrointestinal events. Therefore the determination is non-certification.

**Tramadol ER 150 mg, #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.

**Decision rationale:** With regards to Tramadol, per the CA MTUS Chronic Pain Medical Treatment Guidelines pg 93-94, Tramadol "is a synthetic opioid affecting the central nervous system. Tramadol is not classified as a controlled substance by the DEA. Side Effects: Dizziness, nausea, constipation, headache, somnolence, flushing, pruritus, vomiting, insomnia, dry mouth, and diarrhea. Tramadol may increase the risk of seizure especially in patients taking SSRIs, TCAs and other opioids. Do not prescribe to patients that at risk for suicide or addiction. Warning: Tramadol may produce life-threatening serotonin syndrome, in particular when used concomitantly with SSRIs, SNRIs, TCAs, and MAOIs, and triptans or other drugs that may impair serotonin metabolism. Analgesic dose: Tramadol is indicated for moderate to severe pain. The immediate release formulation is recommended at a dose of 50 to 100mg PO every 4 to 6 hours (not to exceed 400mg/day). This dose is recommended after titrating patients up from 100mg/day, with dosing being increased every 3 days as tolerated. For patients in need of immediate pain relief, which outweighs the risk of non-tolerability the initial starting dose, may be 50mg to 100mg every 4 to 6 hours (max 400mg/day). Ultram ER<sup>®</sup>: Patient currently not on immediate release tramadol should be started at a dose of 100mg once daily. The dose should be titrated upwards by 100mg increments if needed (Max dose 300mg/day). Patients currently on immediate release tramadol calculate the 24-hour dose of IR and initiate a total daily dose of ER rounded to the next lowest 100mg increment (Max dose 300mg/day). (Product information, Ortho-McNeil 2003) (Lexi-Comp, 2008) Tramadol is considered a second line agent when first line agents such as NSAIDs fail. There is insufficient evidence of failure of primary over the counter non-steroids or moderate to severe pain to warrant Tramadol. Therefore use of Tramadol is not medically necessary and it is noncertified.