

<b>Case Number:</b>	CM15-0223176		
<b>Date Assigned:</b>	11/19/2015	<b>Date of Injury:</b>	03/30/2015
<b>Decision Date:</b>	12/30/2015	<b>UR Denial Date:</b>	10/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/12/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. 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 expert 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: North Carolina

Certification(s)/Specialty: Family Practice

### 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 injured worker is a 25 year old male, who sustained an industrial injury on 3-30-2015. According to physician documentation, the injured worker was diagnosed with radiculopathy lumbar sprain, back sprain, cervicgia, lumbar disc placement and esophageal motility disorder/dyspepsia. Subjective findings dated 7-20-2015, 8-20-2015, 9-1-2015 and 9-25-2015 were notable for low back pain that radiates to his left legs and toes with weakness, tingling sensation, popping and cracking sensation of the lower back left leg which is aggravated during movement and alleviated with rest, rating pain 6 out of 10 at best and 9 out 10 at worst stating prescribed medication temporarily alleviates pain. Objective findings dated 7-20-2015, 8-20-2015, 9-1-2015 and 9-25-2015 were notable for tenderness and spasms in the paraspinal muscles, bilateral sacroiliac joints and moderate left paralumbar spinal tenderness with positive left straight leg raise, tenderness of the lumbosacral junction and bilateral flank regions with lumbar flexion of 40 degrees and extension, right lateral bending and left lateral bending of 10 degrees. On 5-27-2015, an MRI of the lumbosacral spine was performed revealing loss of intervertebral disc height at (lumbar) L5-S1 (sacral), grade 1 posterolisthesis present measuring about 3mm and 3.2mm broad based disc protrusion at L5-S1, with mild bilateral facet arthropathy changes, producing mild bilateral spinal and neural foraminal stenosis. On 7-20-2015, and X-ray was performed revealing lumbar spine straightening and reversal of the normal curvature. Treatments to date have included, physical and acupuncture therapy, home exercises, Gabapentin 300mg, Ibuprofen 600mg, Capsaicin cream, Tramadol 50mg, Ketorolac, Orphenadrine ER 100mg, (since at least 8-20-2015), Ketoprofen ER 200 mg (since at least 8-20-2015), Omeprazole DR 20mg (since at least 8-20-2015), and Cyclobenzaprine Hcl 10mg (since at least since 9-2-2015). The Utilization Review determination dated 10-25-2015 did not certify treatment/service requested for Ketoprofen ER 200mg, Omeprazole DR 20mg #30 with 2 refills and Cyclobenzaprine Hcl 10mg #60 with 2 refills.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Ketoprofen ER 200 MG as Needed Qty 30: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID therapy states: Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with Naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008). Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. This medication is recommended for the shortest period of time and at the lowest dose possible. The dosing of this medication is within the California MTUS guideline recommendations. The definition of shortest period possible is not clearly defined in the California MTUS. Therefore, the request is medically necessary.

### **Omeprazole DR 20 MG Qty 30 with 2 Refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID therapy and proton pump inhibitors (PPI) states: Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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 gastro duodenal 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 ug 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. There is no documentation provided that places this patient at intermediate or high risk that would justify the use of a PPI. There is no mention of current gastrointestinal or cardiovascular disease. For these reasons the criteria set forth above per the California MTUS for the use of this medication has not been met. Therefore, the request is not medically necessary.

**Cyclobenzaprine Hydrochloride 10 MG Qty 60 with 2 Refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The California chronic pain medical treatment guidelines section on muscle relaxants states: 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) (Chou, 2004) This medication is not intended for long-term use per the California MTUS. The medication has not been prescribed for the flare-up of chronic low back pain, but rather ongoing back pain. This is not an approved use for the medication. For these reasons, criteria for the use of this medication have not been met. Therefore, the request is not medically necessary.

