

<b>Case Number:</b>	CM15-0125617		
<b>Date Assigned:</b>	07/10/2015	<b>Date of Injury:</b>	02/12/2004
<b>Decision Date:</b>	09/18/2015	<b>UR Denial Date:</b>	06/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/29/2015

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive Medicine

### 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 (IW) is a 60-year-old male who sustained an industrial injury on 02/12/2004. Diagnoses include lumbago, lumbar degenerative disc disease and bulging lumbar disc. Treatment to date has included medications, epidural steroid injections and a trial of a spinal cord stimulator. He walked three times daily on the treadmill, walked his dog and used his spa for treatment of pain. According to the progress notes dated 5/28/15, the IW reported back pain rated 6/10. He did not want to switch pain medication from Norco to Oxycodone; he felt he did best on Norco, maximum of four per day, which he had reduced from five per day. He also reported increased panic attacks when he tried to reduce his Cymbalta dose. He was willing to trial Ben- Gay and Ibuprofen for his chronic osteoarthritis pain and inflammation in place of Voltaren gel, and generic Nexium for the acid reflux he experienced due to NSAID use. Baclofen was planned as a trial in place of Robaxin for his occasional muscle spasms. On examination, his gait was slow and he was unable to balance on the left leg. The lower back was tender to palpation; range of motion was reduced and more painful with extension. Facet loading maneuver was positive and straight leg raise test was positive on the left. Deep tendon reflexes were diminished in the S1 distribution on the left. His pain medications reduced his pain by 30% to 40%, allowing him to walk his dog, perform light work in his garage, stretch and run errands. A request was made for Ben-Gay cream 10-15%, #3; Baclofen 10mg, #60; Cymbalta DR 60mg, #30 with 2 refills; Ibuprofen 800mg, #30 with 2 refills; and Nexium DR 40mg, #30 (generic).

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Bengay cream 10-15% #3: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

**Decision rationale:** MTUS and ODG recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed". The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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 is not recommended". ODG only comments on menthol in the context of cryotherapy for acute pain, but does state "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances causes serious burns, a new alert from the FDA warns". As such, the request for Bengay cream 10-15% #3 is not medically necessary.

**Baclofen 10mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 63-64.

**Decision rationale:** Baclofen is classified as a muscle relaxant. MTUS 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 . . . 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". Additionally, MTUS states "Baclofen (Lioresal, generic available): The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved) (ICSI, 2007)". The treating physician has not provided documentation of muscle spasms related to multiple sclerosis or spinal cord injuries. Additionally, the treating physician has not provided documentation of trials and failures of first line therapies. As such the request for Baclofen 10mg #60 is not medically necessary.

**Cymbalta DR 60mg #30 with 2 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duloxetine (Cymbalta).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Interventions and Treatments Page(s): 15-16.

**Decision rationale:** MTUS state regarding antidepressants for pain; "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur". The treating physician does not indicate failure of first-line agents and does not indicate how a first line agent is ineffective, poorly tolerated, or contraindicated. MTUS states regarding Cymbalta: "Selective serotonin and norepinephrine reuptake inhibitors (SNRIs): Duloxetine (Cymbalta): FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy; Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects: CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs. 2% for placebo), insomnia (8-13% vs. 6-7% for placebo). GI: nausea and vomiting (5-30%), weight loss (2%). . . . . Trial period: Some relief may occur in first two weeks; full benefit may not occur until six weeks. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation". Cymbalta is FDA approved for the treatment of depression and requires continued monitoring for effectiveness per MTUS guidelines. Thus 2 refills would indicate 90 days without additional interim reevaluation. As such, the request for Cymbalta DR 60mg #30 with 2 refills is not medically necessary.

**Ibuprofen 800mg #30 with 2 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Ibuprofen, NSAIDs Page(s): 67-72.

**Decision rationale:** MTUS recommends the use of NSAIDs for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long term use. MTUS states "Ibuprofen (Motrin, Advil [otc], generic available): 300, 400, 600, 800 mg. Dosing: Osteoarthritis and off-label for ankylosing spondylitis: 1200 mg to 3200 mg daily. Individual patients may show no better response to 3200 mg as 2400 mg, and sufficient clinical improvement should be observed to offset potential risk of treatment with the increased dose. Higher doses are generally recommended for rheumatoid arthritis: 400-800 mg PO 3-4 times a day, use the lowest effective dose. Higher doses are usually necessary for osteoarthritis. Doses should not exceed 3200 mg/day. Mild pain to moderate pain: 400 mg PO every 4-6 hours as needed. Doses greater than 400 mg have not provided greater relief of pain". The treating physician did not document a decrease in pain or increase in functional improvement from the use of Ibuprofen to warrant ongoing therapy. As such the request for Ibuprofen 800mg #30 with 2 refills is not medically necessary.

**Nexium Dr 40mg #30-Generic:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** MTUS states "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)." And "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 (200g 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)." ODG states "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)" The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. As such, the request for Nexium Dr 40mg #30-Generic is not medically necessary.