

<b>Case Number:</b>	CM15-0046641		
<b>Date Assigned:</b>	03/18/2015	<b>Date of Injury:</b>	02/13/2013
<b>Decision Date:</b>	04/23/2015	<b>UR Denial Date:</b>	02/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/11/2015

### 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: District of Columbia, Virginia  
Certification(s)/Specialty: Internal 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 is a 55 year old male, who sustained an industrial injury on 02/13/2013. He has reported subsequent bilateral knee pain and was diagnosed with medial meniscus tear and arthritis of the knee. The injured worker was also diagnosed with diabetes and hypertension. Treatment to date has included oral pain medication, surgery and a home exercise program. In a progress note dated 01/28/2015, the injured worker complained of knee pain. Objective findings were notable for an antalgic gait, tenderness along the medial aspect of the knee joint line and positive anterior drawer test on the right. The physician noted that the injured worker would be started on Prilosec due to gastrointestinal irritation with Cymbalta. The physician noted that Cymbalta and Tramadol would also be ordered and that the dose of Tramadol was being increased since the current dose was not efficacious.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Prilosec 20mg #30 with 4 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation <http://reference.medscape.com/drug/prilosec-omeprazole-341997>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG- proton pump inhibitors.

**Decision rationale:** Prilosec 20mg #30 with 4 refills. NON MTUS guidelines Official Disability Guidelines (ODG) ODG Guidelines Chapter: proton pump inhibitors, Rationale for Decision. MTUS does not address this medication. Per ODG: proton pump inhibitors(PPI) are recommended for patients at risk for gastrointestinal events. See NSAIDS, GI symptoms and cardiovascular risk. Prilosec(omeprazole), Prevacid(lansoprazole) and nexium(esomeprazole) are PPIs. Omeprazole provides a statistically significantly greater acid control than lansoprazole (Miner 2010). Healing doses of PPIs are more effective than all other therapies although there is an increase in overall adverse effects to placebo. Nexium and Prilosec are very similar molecules. For many people, Prilosec is more affordable than nexium. Nexium is not available in a generic (as in Prilosec). Also, prilosec is more available as an over the counter product while nexium is not. (Donnellan 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose or the shortest possible amount of time. PPIs are more effective including preventing gastric ulcers induced by NSAIDS. Studies suggest however that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous but much information is available to demonstrate otherwise. If a PPI is used, omeprazole OTC tablets or lansoprazole 24 HR 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 nexium, prevacid, prilosec, protonix, dexilant and aciphex (Shi 2008). A trial of omeprazole or lansoprazole is recommended before nexium therapy. The other PPIs, protonix, dexilant, 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) (Pain Chapter). This patient had developed GI issues after starting cymbalta, however the exact nature of the GI symptoms was not noted. Therefore, this current regimen would not be recommended. Furthermore, cymbalta would not be indicated for this patient. The request is not medically necessary.

**Cymbalta 60mg #30 with 4 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792  
Page(s): 105,15-16.

**Decision rationale:** Per MTUS: SNRIs (serotonin noradrenaline reuptake inhibitors) Recommended as an option in first-line treatment of neuropathic pain, especially if tricyclics are ineffective, poorly tolerated, or contraindicated. See Antidepressants for chronic pain for general guidelines, as well as specific SNRI listing for more information and references. See also Venlafaxine (Effexor) and Duloxetine (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%). Duloxetine can worsen diabetic control in some patients. It also causes sexual dysfunction. (Maizels, 2005) Dosing: 60 mg once a day as an off-label option for chronic pain syndromes. Dosage adjustment may be required in patients with renal insufficiency. Venlafaxine (Effexor): FDA-approved for anxiety, depression, panic disorder and social phobias. Off-label use for fibromyalgia, neuropathic pain, and diabetic neuropathy. Side-effect profile: CNS: (5%) drowsiness, weakness, dizziness, dry mouth, insomnia, nervousness/anxiety (13/6% vs. 6/3%), tremor, headache, seizures. GI: N&V, constipation, weight loss (2-18%). Pre existing hypertension should be controlled. Cholesterol may be increased (5%). Sexual dysfunction has also been noted. (Maizels, 2005) (ICSI, 2007) Dosing: Neuropathic pain (off label indication): 37.5 mg once daily, increase by 37.5 mg per week up to 300 mg daily. (Maizels, 2005) (ICSI, 2007) 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. The patient did not achieve pain relief while on this medication. A weaning process should be initiated. The request is not medically necessary.

**Tramadol 50mg #150 with 2 refills:** Overtaken

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram), Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792 Page(s): 75, 80.

**Decision rationale:** Per MTUS: Central acting analgesics: an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g., Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram) are reported to be effective in managing neuropathic pain. (Kumar, 2003) Side effects are similar to traditional opioids. For chronic back pain: There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007) The patient had chronic pain issues. This medication would be indicated. The request is medically necessary.