

<b>Case Number:</b>	CM15-0094993		
<b>Date Assigned:</b>	05/21/2015	<b>Date of Injury:</b>	05/07/2012
<b>Decision Date:</b>	06/24/2015	<b>UR Denial Date:</b>	05/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/18/2015

### 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: California

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:

This then said 52 year old male sustained an industrial injury on 05/07/2012. According to a progress report dated 01/26/2015, the injured worker complained of low back pain with right lower extremity symptoms. Low back pain was rated 6 on a scale of 1-10. Cervical pain with left greater than right upper extremity symptoms was reported. Cervical pain was rated 5 on a scale of 1-10. Left knee pain was rated 7. Medication regimen included Hydrocodone, Pantoprazole, Cyclobenzaprine and Naproxen. Physical examination demonstrated tenderness of the left knee, swelling of the left knee, crepitance with range of motion. Lumbar range of motion was limited with pain. Straight leg raise was positive on the right. Cervical range of motion percent of normal was flexion 50, extension 40, left and right rotation 50 and left and right lateral tilt 50. Upper extremity neurological evaluation was unchanged. Diagnoses included cervical myofascial pain, status post left knee surgery on 08/2013 and protrusion L5-S1. Treatment plan included additional postoperative physical therapy for the left knee. Medications prescribed included Hydrocodone, Pantoprazole, Cyclobenzaprine and Naproxen. According to a progress report dated 02/23/2015, subjective complaints and pain levels remained unchanged from the previous visit. Physical examination demonstrated tenderness of the left knee, swelling of the left knee, crepitance with range of motion. Lumbar exam demonstrated tenderness diffusely. Lumbar range of motion was limited with pain. Straight leg raise was positive on the right. Cervical range of motion percent of normal was flexion 50, extension 40, left and right rotation 50 and left and right lateral tilt 50. Upper extremity neurological evaluation was unchanged. Medication regimen included Hydrocodone, Cyclobenzaprine, Naproxen and Pantoprazole. On 03/30/2015, the injured worker complained of low back pain with right lower extremity symptoms and cervical pain with left greater than right upper extremity symptoms. Low back pain was rated 6 on a scale of 1-10. Cervical pain was rated 5 and knee pain was rated

7. Pain levels were unchanged from the previous examination on 02/23/2015. Physical examination was unchanged from previous. The provider noted that the medication at the current dosing facilitated maintenance of activities of daily living including light household duties, shopping for groceries, grooming and cooking. Without medication, the injured worker was unable to adhere to recommended exercise regimen. Medications dispensed included Duloxetine, Naproxen, Pantoprazole and Cyclobenzaprine. On 04/27/2015, the injured worker complained of left knee pain that was rated 5 on a scale of 1-10. Low back pain with right lower extremity symptoms was rated 5. Physical examination remained unchanged from previous. The provider noted that Duloxetine facilitated 4-6 diminution in pain as well as significant increase in tolerance to a variety of activity, greater function and improved range of motion. Non-steroidal anti-inflammatory drugs facilitated improved range of motion and decreased achy pain an additional 3 point average. The injured worker recalled history of gastrointestinal upset with non-steroidal anti-inflammatory drugs with no proton pump inhibitor. Prior to Cyclobenzaprine, spasms were refractory to activity modification, stretching, heat, physical therapy and home exercise. Cyclobenzaprine decreased spasm for approximately 4-6 hours, facilitated marked improved range of motion, tolerance to exercise and additional decrease in overall pain level average 3-4 points. Medications dispensed included Duloxetine, Naproxen, Pantoprazole and Cyclobenzaprine. Currently under review is the request for retro Duloxetine, retro Pantoprazole and retro Cyclobenzaprine.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **RETRO Duloxetine 30mg #60 for DOS 03-30-2015: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duloxetine Page(s): 43-44.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment guidelines comment on the use of Duloxetine as a treatment modality. Duloxetine is recommended as an option in first-line treatment option in neuropathic pain. Duloxetine (Cymbalta) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). The starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. The medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. In this case, there is insufficient documentation in support of the diagnosis of neuropathic pain as the cause of this patient's symptoms. There is no evidence that the patient has fibromyalgia, depression or generalized anxiety disorder; which are additional conditions in which Duloxetine is recommended. Given that there is no documentation in support for the use of this medication, Duloxetine is not considered as a medically necessary treatment.

#### **RETRO Pantoprazole 20mg #60 for DOS 03-30-2015: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 22, 67-68.

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

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment guidelines comment on the use of proton pump inhibitors (PPIs) such as pantoprazole, as a treatment modality. These guidelines state that in assessing the need for a PPI, clinicians should determine if the patient is at risk for gastrointestinal events. These risk factors are: (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 g 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. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. In this case the medical records indicate that the patient has no risk factors for a gastrointestinal event. With no documented risk factors, these above cited guidelines do not support the need for a PPI. For this reason, Pantoprazole is not considered as a medically necessary treatment.

**RETRO Cyclobenzaprine 7.5mg #90 for DOS 03-30-2015:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment guidelines comment on the use of muscle relaxants such as Cyclobenzaprine as a treatment modality. Cyclobenzaprine is 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. In this case, the records indicate that Cyclobenzaprine is being used as a long-term treatment for this patient's myofascial pain syndrome. As noted in the above cited guidelines, only short-term treatment is recommended. There is no rationale provided to justify long-term use. For this reason, Cyclobenzaprine is not considered as a medically necessary treatment.