

<b>Case Number:</b>	CM15-0059410		
<b>Date Assigned:</b>	04/03/2015	<b>Date of Injury:</b>	10/28/1997
<b>Decision Date:</b>	05/05/2015	<b>UR Denial Date:</b>	02/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/30/2015

### 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:

The injured worker is a 74-year-old male, who sustained an industrial injury on 10/28/97. The diagnoses have included chronic low back pain and bilateral shoulder pain. Treatment to date has included medications, diagnostics, orthopedic specialist and Home Exercise Program (HEP). The diagnostic studies included x-ray and Computed Tomography (CT) scan. The current medications included Norco, Ambien, Cymbalta and Naprosyn. Currently, as per the physician progress note dated 2/10/15, the injured worker complains of bilateral shoulder and low back pain. The pain in the low back was rated 8/10 on pain scale and the shoulder was rated 5/10. The low back pain radiates to the right thigh and he states that the medications provide him with relief and he is able to sleep well. It was noted that there was no significant changes in the objective findings. The physician requested treatments included Retrospective Cymbalta 30mg, #120 (DOS 2/10/2015) and Retrospective Naprosyn 500mg, #120 (DOS 2/10/2015).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Cymbalta 30mg, #120 (DOS 2/10/2015): Upheld**

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

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

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of Duloxetine (Cymbalta) for the treatment of pain. The MTUS guidelines recommend Duloxetine 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. In this case, the last available progress note indicated that the patient was being prescribed Duloxetine 30 mg BID. Therefore, a monthly supply should require 60 tablets. In the Utilization Review process, it was noted that the MTUS indications for the use of Duloxetine were met; and I agree with this statement. However, the patient had been receiving excess number of pills for a one-month supply. The non-certification was based only for this reason. Per the above cited guidelines and the last documented dosing schedule for Duloxetine (30 mg BID) a monthly prescription should be no more than 60 tablets. For this reason, Duloxetine (Cymbalta) 30 mg #120 (DOS 2/10/2015) is not medically necessary.

**Retrospective Naprosyn 500mg, #120 (DOS 2/10/2015): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68, 73.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of NSAIDs, such as Naprosyn, as a treatment modality. These guidelines provide specific recommendations for the use of NSAIDs. These specific recommendations are as follows: Osteoarthritis (including knee and hip): 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. Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 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. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects.

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. The MTUS Guidelines also comment on the dosing of Naprosyn. Dosing recommendations are as follows: (Naprosyn): 250-500 mg twice daily. The maximum dose on day one should not exceed 1250 mg and 1000 mg on subsequent days. In this case, in the Utilization Review process, while it was felt that there were indications to the chronic use of Naprosyn, the number of pills exceeded the MTUS recommendations for a monthly supply as the patient had previously received a two-month supply of this drug. The MTUS guidelines indicate that 60 tablets of Naprosyn 500 mg would be appropriate as a one-month supply. Therefore, Naprosyn 500 mg #120 tablets (DOS 2/10/2015) is not medically necessary.