

<b>Case Number:</b>	CM15-0026867		
<b>Date Assigned:</b>	02/19/2015	<b>Date of Injury:</b>	11/18/2011
<b>Decision Date:</b>	03/27/2015	<b>UR Denial Date:</b>	01/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/12/2015

### 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 44 year old female, who sustained an industrial injury on 11/18/2011. The diagnoses have included chronic recurrent major depressive disorder. Noted treatments to date have included heat/cold therapy, epidural steroid injection, physical therapy, Transcutaneous Electrical Nerve Stimulation Unit, chiropractic treatment, cognitive behavioral therapy, and medications. Diagnostics to date have included MRI which revealed three bulging discs in her neck as well as impingement in her left shoulder per progress notes. In a progress note dated 12/23/2014, the injured worker presented with complaints of continued neck and shoulder pain, decreased interest in doing things, and feeling down and depressed. The treating physician reported prescribing Cymbalta 30mg daily at bedtime every other night alternating with Cymbalta 60mg at bedtime every other night. Utilization Review determination on 01/23/2015 non-certified the request for Cymbalta 30mg and Cymbalta 60mg citing Medical Treatment Utilization Schedule Chronic Pain Medical Treatment Guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cymbalta 30mg:** Overturned

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

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

**Decision rationale:** The California chronic pain medical treatment guidelines section on Duloxetine states: Duloxetine (Cymbalta) 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. (Arnold, 2005) 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. Note: On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with hepatic insufficiency. See also Antidepressants for chronic pain for general guidelines, as well as specific Duloxetine listing for more information and references. On June 13, 2008, the FDA approved a new indication for duloxetine HCl delayed-release capsules (Cymbalta; [REDACTED]) for the management of fibromyalgia in adults. The FDA notes that although duloxetine was effective for reducing pain in patients with and without major depressive disorder, the degree of pain relief may have been greater in those with comorbid depression. Treatment of fibromyalgia with duloxetine should be initiated at 30 mg/day for 1 week and then up titrated to the recommended 60-mg dose. (Waknine, 2008) Note: This drug was recently included in a list of 20 medications identified by the FDA's Adverse Event Reporting System, that are under FDA investigation. (FDA, 2008) The requested medication is a first line option in the treatment of neuropathic pain per the California MTUS. Per the progress notes the patient has persistent and constant neuropathic pain. The patient has no indication of hepatic disease so there would be no major contraindications to the medication. The patient also has major depression disorder, which this medication is indicated for. For these reasons, criteria for use of the medication have been met and the request is certified.

**Cymbalta 60mg:** Overturned

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

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

**Decision rationale:** The California chronic pain medical treatment guidelines section on Duloxetine states: Duloxetine (Cymbalta) 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. (Arnold, 2005) 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. Note: On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with hepatic insufficiency. See also Antidepressants for chronic pain for general guidelines, as well as specific Duloxetine listing for more information and references. On June 13, 2008, the FDA approved a new indication for duloxetine HCl delayed-release capsules (Cymbalta; [REDACTED]) for the management of fibromyalgia in adults. The FDA notes that although duloxetine was effective for reducing pain in patients with and without major depressive disorder, the degree of pain relief may have been greater in those with comorbid depression. Treatment of fibromyalgia with duloxetine should be initiated at 30 mg/day for 1 week and then up titrated to the recommended 60-mg dose. (Waknine, 2008) Note: This drug was recently included in a list of 20 medications identified by the FDA's Adverse Event Reporting System, that are under FDA investigation. (FDA, 2008) The requested medication is a first line option in the treatment of neuropathic pain per the California MTUS. Per the progress notes the patient has persistent and constant neuropathic pain. The patient has no indication of hepatic disease so there would be no major contraindications to the medication. The patient also has major depression disorder, which this medication is indicated for. For these reasons, criteria for use of the medication have been met and the request is certified.