

<b>Case Number:</b>	CM15-0106919		
<b>Date Assigned:</b>	06/11/2015	<b>Date of Injury:</b>	10/31/1997
<b>Decision Date:</b>	07/13/2015	<b>UR Denial Date:</b>	05/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/03/2015

### 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 66 year old female patient who sustained an industrial injury on 10/31/1997. The patient was working at a dean's office in a school she developed symptoms of fibromyalgia as well as joint pains, rashes and mouth ulcers. She has a medical history of fibromyalgia, anemia, and history of pneumonia, cataracts and headaches. Prior surgical history to include: narcotic pump placement in 2012; removal of bone growth stimulator in 2011, lumbar laminectomy with spinal fusion in 2010; trigger thumb release and carpal tunnel release in 2006; anterior lumbar interbody fusion in 2006; exploratory spinal fusion; lumbar laminectomy in 2003, 2004, and 2005; multiple rotator cuff repairs to bilateral shoulders 1983-1995. Active medications are: Tylenol, Ambien, Colace, Cymbalta, Dilaudid, Iron, Lidoderm, Reglan, Mobic, Neurontin, Nexium, Senna and Trazadone. The assessment found the patient with: fibromyalgia with chronic pain component, history of Lupus, chronic constipation, Fatigue with low DHEA, rash on left upper and lower extremities, and left knee osteoarthritis, degenerative joint disease. She is to continue with current medications and left knee replacement with rehabilitation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cymbalta 60mg #60 with 4 refills:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

**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. Post-marketing 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; Eli Lilly and Company) 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 uptitrated 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 and fibromyalgia. Per the progress notes the patient has persistent fibromyalgia. The patient has no indication of hepatic disease so there would be no major contraindications to the medication. For these reasons criteria for use of the medication have been met and the request is medically necessary.