

<b>Case Number:</b>	CM15-0132735		
<b>Date Assigned:</b>	07/20/2015	<b>Date of Injury:</b>	10/01/2000
<b>Decision Date:</b>	08/14/2015	<b>UR Denial Date:</b>	06/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/09/2015

### 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 55-year-old male who sustained an industrial injury on 10/01/2000. Mechanism of injury was cumulative trauma to his spine and bilateral knees secondary to his years in construction. Diagnoses include anxiety, adjustment disorder with depressed mood, arthropathy, knee joint stiffness, hypertension, degenerative cervical disc disease, degenerative lumbar disc disease, sleep apnea, facet arthropathy, personal history of tobacco abuse and psychosexual dysfunction. Treatment to date has included diagnostic studies, medications, status post anterior fusion from C5 through T1, and facet injections. He has not worked since the year 2000. He has done well with high-dose opioids; he needs Testosterone replacement and Cymbalta for his mood, energy and sleep. His medications also include Oxy Contin 80mg three times a day and Oxycodone 15mg every 7 hours. A physician progress note dated 05/20/2015 documents the injured worker complains of back pain that is moderate to severe. It is located in his upper back, middle back and low back, gluteal area, neck and thighs. Pain radiates to the left thigh and right thigh. Pain is described as an ache, burning, deep, dull, sharp, shooting, stabbing and throbbing and there is numbness. He rates his pain without medications as 9 on a scale of 0 to 10, and with his medications his pain is 5 out of 10. In the last month, he rates his pain as 8 on a scale of 0 to 10. He rates how much his pain has interfered with activities of daily living in the last month as a 9 on a scale of 0 to 10. He has numbness in extremities. He has anxiety, depression and insomnia. His cervical spine, thoracic spine and lumbar spine have tenderness and restricted range of motion with pain. The treatment plan includes prescribed medications of OxyContin, and Oxycodone Hcl. Treatment requested is for Cymbalta 60mg, #30 with 4 refills.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Cymbalta 60mg, #30 with 4 refills:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Selective serotonin and norepinephrine reuptake inhibitors (SNRIs).

**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, [REDACTED] 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; [REDACTED] 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. Per the progress notes, the patient has persistent and constant neuropathic pain. As well as anxiety and depression. 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.