

<b>Case Number:</b>	CM15-0052308		
<b>Date Assigned:</b>	04/28/2015	<b>Date of Injury:</b>	11/02/1999
<b>Decision Date:</b>	05/22/2015	<b>UR Denial Date:</b>	03/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/19/2015

### 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 55 year old female, who sustained an industrial injury on November 2, 1999. The injured worker has been treated for bilateral hip, bilateral upper extremity and bilateral lower extremity complaints. The diagnoses have included lower extremity reflex sympathetic dystrophy, bilateral hip pain, lumbar pain, anxiety, depression, chronic insomnia and complex regional pain syndrome of the right upper extremity with spread to the lower extremities. Treatment to date has included medications and a home exercise program. Other prior conservative treatments were not found in the documentation submitted. Current documentation dated March 16, 2015 notes that the injured worker reported headaches, bilateral hip pain, bilateral upper extremity pain and bilateral lower extremity pain. The injured workers pain was noted to have worsened since the prior visit. The average pain level was noted to be an eight out of ten on the visual analogue scale with medications. The injured worker was noted to have more problems with ambulation due to the increased hip pain. Examination of the lower extremities revealed tenderness to palpation of the right knee and positive allodynia about the right knee and bilateral lower extremities. Bilateral hip pain was noted with internal and external rotation of the hips. The treating physician's plan of care included a request for the medications Cymbalta and Lyrica.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cymbalta 60mg, #60:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic).

**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. 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 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. 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 certified.

**Lyrica 200mg, #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drug.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica  
Page(s): 19.

**Decision rationale:** The California chronic pain medical treatment guidelines section on Lyrica states: Pregabalin (Lyrica, no generic available) has been documented to be effective in treatment of diabetic neuropathy and post herpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced the approval of pregabalin as the first approved treatment for fibromyalgia. (ICSI, 2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008) The patient does not have the diagnoses of diabetic neuropathy, fibromyalgia or post herpetic neuropathy. There is no documentation of failure of other first line agents for peripheral neuropathy. Therefore guideline recommendations have not been met and the request is not certified.