

<b>Case Number:</b>	CM15-0086652		
<b>Date Assigned:</b>	05/08/2015	<b>Date of Injury:</b>	03/29/2000
<b>Decision Date:</b>	06/09/2015	<b>UR Denial Date:</b>	04/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/05/2015

### 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 49 year old female who sustained an industrial injury on March 29, 2000. Previous treatment includes medications and surgical intervention. Currently the injured worker complains of low back pain, chronic pain syndrome, anxiety and stress. Diagnoses associated with the request include lumbago. The treatment plan includes medications of methadone, Lyrica, soma, OxyContin, duloxetine and follow-up evaluation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Methadone 10mg, #84:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines methadone Page(s): 61-62.

**Decision rationale:** The California chronic pain medical treatment guidelines section on methadone states: Methadone Recommended as a second-line drug for moderate to severe pain

if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it. (Clinical Pharmacology, 2008) Steps for prescribing methadone: (1) Basic rules-Weigh the risks and benefits before prescribing methadone. Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction. Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments. (2) Know the information that is vital to give the patient: Don't be tempted to take more methadone than prescribed if you are not getting pain relief. This can lead to a dangerous build-up that can cause death. All changes in methadone dose should be made by your treating practitioner. Methadone can make your breath slow down, or actually stop. Methadone can slow down your heartbeat and you might not be able to detect this. If you feel like you are having an irregular heartbeat, dizziness, light-headedness or fainting, call your doctor or clinic immediately. (FDA, 2006) (3) Be familiar with the current SAMHSA health advisory on methadone. The medication has become more accessible to unauthorized users. It can accumulate in potentially harmful doses (especially during the first few days of treatment. There has been a rise in Methadone-associated mortality. (SAMHSA, 2004) (4) Be familiar with the FDA final policy statement on Methadone that explicitly discusses the topic, "Can Methadone be used for pain control?" No separate registration is required to prescribe methadone for treatment of pain. (DEA, 2006) (5) Read the new prescribing information for Methadone and the new patient information section. (Roxane, 2006) (6) Multiple potential drug-drug interactions can occur with the use of Methadone. A complete list of medications should be obtained prior to prescribing methadone to avoid adverse events, and the patient should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications. This medication is indicated as a second-line agent in the treatment of chronic pain. The long-term use of opioid therapy is only indicated when measurable outcomes in pain control and function have been achieved. The included clinical documentation for review does not show failure of all first line pain agents. The provided documentation fails to show these measurable outcome improvements, Therefore the request has not met criteria as per the California MTUS guidelines and is not medically necessary.

**Lyrica 50mg, #90:** Upheld

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

**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 medically necessary.

**Duloxetine 60mg, #90:** Overturned

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

**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 as well as depression/anxiety. 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.