

Case Number:	CM15-0177476		
Date Assigned:	09/18/2015	Date of Injury:	09/13/2006
Decision Date:	10/20/2015	UR Denial Date:	08/21/2015
Priority:	Standard	Application Received:	09/09/2015

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 45 year old male who sustained an industrial injury on 9-13-06. Diagnoses are noted as lumbar disc degeneration, chronic pain-other, lumbar disc displacement, failed back surgery syndrome-lumbar, lumbar post laminectomy syndrome, lumbar radiculitis, lumbar radiculopathy, status post fusion-lumbar spine, status post removal of hardware, anxiety, depression, obesity, failed epidurals, and failed spinal cord stimulator trials. In a progress report dated 7-31-15, the physician notes complaints of constant low back pain that radiates down the bilateral lower extremities accompanied by numbness and tingling. Pain is aggravated by activity, bending, prolonged sitting, standing, twisting and walking. He reports severe difficulty with sleep and has muscle spasms in the low back. Pain on average with medications is rated at 6 out of 10, without medications is at 9 out of 10. He reports his pain has worsened since last visit and ongoing limitations with activities of daily living. It is noted that medications are helping him function and they are attempting to wean narcotics. He was given a Toradol-B12 injection at this visit. Examination reveals, a slow antalgic gait and he utilizes a cane for ambulation. Tenderness to palpation of the lumbar spinal vertebral area is noted at the L4-S1 levels and range of motion is moderately to severely limited. Pain was noted to be significantly increased with flexion and extension. There is decreased sensitivity to touch along the L4-S1 dermatome and decreased strength in bilateral lower extremities. Seated straight leg raise was positive bilaterally at 45 degrees. It is noted he is not currently working. The requested treatment of Cyclobenzaprine 7.5mg #30, Duloxetine DR 30mg #30, and Lyrica 100mg #60 was non-certified on 8-21-15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine 7.5mg #30 SIG: take 1 by mouth twice daily as needed for spasm #60:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: The California chronic pain medical treatment guidelines section on muscle relaxants states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) (Chou, 2004) This medication is not intended for long-term use per the California MTUS. The medication has not been prescribed for the flare-up of chronic low back pain but rather ongoing back pain This is not an approved use for the medication. For these reasons, criteria for the use of this medication have not been met. Therefore, the request is not medically necessary.

Duloxetine Dr 30mg #30 SIG take 1 daily qty: 30: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain.

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 anti-depressant (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; ██████████) 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 co-morbid 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 medically necessary.

Lyrica 100mg capsule SIG take 1 by mouth twice daily qty 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

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.