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| Case Number: | CM15-0071227 | | |
| Date Assigned: | 04/21/2015 | Date of Injury: | 09/21/2011 |
| Decision Date: | 05/27/2015 | UR Denial Date: | 04/02/2015 |
| Priority: | Standard | Application Received: | 04/14/2015 |

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 32-year-old male, who sustained an industrial injury on 09/21/2011. He reported that he was changing a paper cartridge in a printing machine with the cartridge weighing about 20 to 30 pounds. As the injured worker lifted the cartridge, he twisted his left upper extremity, neck, and back awkwardly causing him to feel a pop in his left wrist followed by sharp neck and back pain. The injured worker was diagnosed as having cervical radiculopathy, lumbar radiculopathy, upper mid back pain, and rule out reflex sympathetic dystrophy. Treatment to date has included epidural injection, use of heat, medication regimen, magnetic resonance imaging of the cervical spine, magnetic resonance imaging of the left shoulder, and magnetic resonance imaging of the left wrist. In a progress note dated 07/31/2014 the treating physician reports complaints of neck pain that is rated a six to seven on the visual analog scale of zero to ten, left shoulder pain that is rated a seven to eight on the visual analog scale, left wrist pain that is rated a seven to eight on the visual analog scale that radiates to the left elbow, low back pain that is rated a six to seven on the visual analog scale that radiates to the lower extremities, and upper mid back pain that is rated a six to seven on the visual analog scale that radiates to the lower extremities. The documentation provided did not contain the request of the medication Cymbalta 30mg with a quantity of 30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 30 mg Qty 30: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cymbalta (duloxetine) Page(s): 42.

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 up titrated 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.