

<b>Case Number:</b>	CM13-0033429		
<b>Date Assigned:</b>	12/06/2013	<b>Date of Injury:</b>	03/30/2012
<b>Decision Date:</b>	02/05/2014	<b>UR Denial Date:</b>	09/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/09/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Psychiatry & Neurology, has a subspecialty in Geriatric Psychiatry, Addiction Medicine, and is licensed to practice in California. 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 physician 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

8/26/13 Neurological consultation shows positive Tinel sign in right posterior radial tunnel, negative in right median wrist/ulna/cubital nerve. There were no vasomotor or sudomotor manifestations of increased sympathetic tone in the right upper extremity. He notes the 4/23/13 primary treating progress note symptoms of pain level of 7/10 with tenderness of the medial epicondyle and cubital tunnel with dysesthesias and hyperesthesias and local Tinel sig, with distal radiation into the thumb and mid-dorsal arm, as well as tenderness of the right proximal forearm muscles and first dorsal compartment. He also mentions the 6/4/13 primary treating physician progress report in which the claimant complains of right elbow pain and right thumb numbness and tingling, as well as median distribution pain/numbness and tingling with pain from 2-7/10. At that time she was given a prescription for Lyrica. This consulting neurologist recommended a trial of Cymbalta 60mg per day for the management of both musculoskeletal and neuropathic pain. On 9/18/13 the primary treating physician's report shows that the claimant presented with right upper extremity strain injury, with significant neuropathic pain and secondary chronic pain ranging from 3-7/10, substantially in the right lateral forearm with some improvement in the numbness into the right thumb. As she had taken Cymbalta samples in the past (speculated to be 30mg for perhaps several weeks) and noticed no change, this provider recommended Cymbalta 30mg 2 po daily, adjust dose as directed with 2 refills, continuing Voltaren gel, and MRI of right elbow and forearm to evaluate for cubital tunnel syndrome, ulnar nerve entrapment at the elbow, and radial tunnel entrapment of the right forearm. It should be noted that in a QME report dated 10/14/13 there is a date of injury of 11/5/07. In this report apparently the claimant was diagnosed in 2001 with left carpal tunnel syndrome, which recurred in 2004. At that time she also de

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Cymbalta 30mg #60 2 PO QD, with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duloxetine (Cymbalta)..

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Specific Antidepressants, Selective Serotonin Reuptake Inhibitors (SNRI's), Page(s): 15-16.

**Decision rationale:** This patient has a complex pain presentation of which only one part represents true neuropathic pain. Duloxetine (Cymbalta) is a serotonin norepinephrine reuptake inhibitor which was FDA approved for the treatment of depression, anxiety, and diabetic neuropathy. It is also approved for fibromyalgia. This is noted in CA-MTUS 2009. It does not carry the approval for the type of radicular pain this claimant is suffering from. It represents an off label use for her chronic pain presentation, as such it cannot be approved under CA-MTUS guidelines. The request is therefore denied. Per CA-MTUS 2009: Selective serotonin and norepinephrine reuptake inhibitors (SNRIs): Duloxetine (Cymbalta®): FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects: CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs.2% for placebo), insomnia (8-13% vs. 6-7% for placebo). GI: nausea and vomiting (5-30%), weight loss (2%). Duloxetine can worsen diabetic control in some patients. It also causes sexual dysfunction. (Maizels, 2005) Dosing: 60 mg once a day as an off-label option for chronic pain syndromes. Dosage adjustment may be required in patients with renal insufficiency. Recommended. Duloxetine (Cymbalta), an inhibitor of serotonin and norepinephrine reuptake, has been approved for the treatment of major depressive disorder. Duloxetine has been shown to be effective in the treatment of first and subsequent episodes of major depressive disorder, and regardless of duration of the current depressive episode. (Perahia, 2006) (Fava, 2004) (Nelson, 2005) (Bymaster, 2005) (Brannan, 2005) (Acharya, 2006) One meta-analysis examining potential gender differences in the efficacy of duloxetine concluded that efficacy did not differ significantly in male and female patients. (Kornstein, 2006) Cymbalta, an SNRI from Lilly, has been approved by the FDA for both the treatment of depression and the management of pain associated with depression. Serotonin and norepinephrine, that are believed to play a role in how the brain and body affect mood and pain. 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 (duloxetine hydrochloride), indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. 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