

Case Number:	CM14-0160748		
Date Assigned:	10/06/2014	Date of Injury:	01/22/1998
Decision Date:	04/23/2015	UR Denial Date:	09/02/2014
Priority:	Standard	Application Received:	09/30/2014

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: New York, Tennessee
 Certification(s)/Specialty: Emergency Medicine

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 50-year-old female, with a reported date of injury of 01/22/1998. The diagnoses include severe major depressive disorder and pain disorder. Treatments to date have included physical therapy, psychotherapy, pain management, and oral medications. The progress report dated 08/01/2014 indicates that the injured worker was more depressed since her Cymbalta was switched to generic Duloxetine. She found herself groggy on Lunesta. The focused mental status examination showed alert and oriented, well-groomed, well-related, cooperative, soft speech, coherent, an affect that was constricted in range, a frustrated mood, signs of psychomotor slowing, no delusions, no suicidal ideation, and intact judgment and insight. The treating physician requested Cymbalta 30mg, 30 per month for eighteen months; Lunesta 1mg, 30 per month for eighteen months; and Cymbalta 60mg, 30 per month for eighteen months. The injured worker was converted back to the branded Cymbalta, and was to restart Lunesta for sleep.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 30mg DAW 30 per month for 18 months: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-14.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 15-16. Decision based on Non-MTUS Citation The Medical Letter On Drugs and Therapeutics: Vol. 44 (W1141C) pg 89-90, Generic Drugs.

Decision rationale: Cymbalta is duloxetine, a selective serotonin and norepinephrine reuptake inhibitors (SNRI). It is 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. No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects include dizziness, fatigue, somnolence drowsiness, anxiety and insomnia. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation. In this case the request was for brand name medication instead of generic duloxetine. No well-documented therapeutic differences between brand-name originals and FDA-approved generics have been reported. There is no medical necessity for brand name Cymbalta. The request is not medically necessary.

Lunesta 1mg DAW 30 per month for 18 months: Upheld

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 Chapter, Insomnia Treatment.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain Insomnia Treatment The Medical Letter On Drugs and Therapeutics: Vol. 44 (W1141C) pg 89-90, Generic Drugs.

Decision rationale: Insomnia treatment should be based on etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Lunesta is the non-benzodiazepine sedative hypnotic medication, eszopiclone, recommended as first line medication for insomnia. It is a benzodiazepine-receptor agonist which works by selectively binding to type-1 benzodiazepine receptors in the CNS. All of the benzodiazepine-receptor agonists are schedule IV controlled substances, which means they have potential for abuse and dependency. It is the only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. A randomized, double blind, controlled clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the control group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period. Side effects are dry mouth, unpleasant taste, drowsiness, dizziness. Sleep-related activities such as driving, eating, cooking and phone calling have occurred. Withdrawal may occur with abrupt discontinuation. Dosing is 1-2 mg for difficulty falling asleep and 2-3 mg for sleep maintenance. The drug has a rapid onset of action. In this case the patient had been using the medication since August 2014 and was still experiencing sleep problems. In addition

the patient is requesting brand name Lunesta. No well-documented therapeutic differences between brand-name originals and FDA-approved generics have been reported. There is no medical necessity for brand name Lunesta. The request is not medically necessary.

Cymbalta 60mg DAW 30 per month for 18 months: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-14.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 15-16. Decision based on Non-MTUS Citation The Medical Letter On Drugs and Therapeutics: Vol. 44 (W1141C) pg 89-90, Generic Drugs.

Decision rationale: Cymbalta is duloxetine, a selective serotonin and norepinephrine reuptake inhibitors (SNRI). It is 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. No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects include dizziness, fatigue, somnolence drowsiness, anxiety and insomnia. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation. In this case the request was for brand name medication instead of generic duloxetine. No well-documented therapeutic differences between brand-name originals and FDA-approved generics have been reported. There is no medical necessity for brand name Cymbalta. The request is not medically necessary.