Medical Review Institute of America, Inc.
America's External Review Network

IRO Case #:

Description of the services in dispute:
Prescribed medication – Cymbalta

A description of the qualifications for each physician or other health care provider who reviewed the decision
This physician reviewer is board certified by the American Board of Neurological Surgery in Neurological Surgery. This reviewer is a member of the American Medical Association, Congress of Neurological Surgeons, American Association of Neurological Surgeons and AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves.

Review Outcome
Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld

The medical necessity is not established for the prescribed medication Cymbalta.

Information provided to the IRO for review
Records from the State:
Company request for IRO, 2/12/10, 5pgs.
Request For A Review By An Independent Review Organization, 2/6/10, 3pgs.
Injury Management Organization (IMO), Adverse Determination Letter, 1/5/10, 2 pgs.
IMO, Adverse Determination Letter, 12/8/09
Records from IRO Coordinator:
Dr., Copy of Report, 8/6/06, 2pgs.
Dr., Letter of Denial, 12/8/09, 1 pg.
Care, Medicare Coverage Determination Request Form, 12/3/09
, Office Visit Note, 8/6/06, 4 pgs.
, Office Visit Note, 10/21/09, 2pgs. Dr., Evaluation,
12/5/09, 14 pgs.
Letter of Appeal, 8/6/06, 1 pg.
Psychological Evaluation, 11/17/09, 6 pgs.
Medical Records from Provider:
Orthopaedic Center, Office Visit Note, 1/22/10, 5pgs.
Orthopaedic Center, Office Visit Note, 11/25/09, 4pgs.

Orthopaedic Center, Office Visit Note, 9/30/09, 4pgs.
Orthopaedic Center, Imaging Report, 9/16/09, 2pgs.
Orthopaedic Center, Office Visit Note, 9/9/09, 4pgs.
Orthopaedic Center, Office Visit Note, 7/10/09, 5pgs.
Orthopaedic Center, Office Visit Note, 5/27/09, 4pgs.
Orthopaedic Center, Office Visit Note, 3/25/09, 4pgs.
Orthopaedic Center, Office Visit Note, 1/15/09, 5pgs.
Orthopaedic Center, Office Visit Note, 12/5/08, 4pgs.
Orthopaedic Center, Office Visit Note, 10/23/08, 5pgs.
Orthopaedic Center, Office Visit Note, 8/13/08, 4pgs.
Orthopaedic Center, Office Visit Note, 7/11/08, 4pgs.
Orthopaedic Center, Office Visit Note, 6/11/08, 4pgs.
Orthopaedic Center, Office Visit Note, 4/10/08, 4pgs.
Orthopaedic Center, Office Visit Note, 1/4/08, 4pgs.
Orthopaedic Center, Office Visit Note, 11/28/07, 4pgs.
Dr., Operative Note, 11/13/07, 1pg.
Orthopaedic Center, Office Visit Note, 10/24/07, 3pgs.
Orthopaedic Center, Office Visit Note, 10/19/07, 4pgs.
Orthopaedic Center, Office Visit Note, 10/4/07, 3pgs.
Orthopaedic Center, Office Visit Note, 9/20/07, 5pgs.
Orthopaedic Center, Office Visit Note, 8/1/07, 2pgs.
Orthopaedic Center, Office Visit Note, 7/26/07, 4pgs.
Orthopaedic Center, Office Visit Note, 6/27/07, 4pgs.
Orthopaedic Center, Office Visit Note, 6/6/07, 3pgs
Orthopaedic Center, Five View Report, 6/6/07, 1 pg.
Orthopaedic Center, Office Visit Note, 5/24/07, 4pgs.
Orthopaedic Center, Office Visit Note, 5/9/07, 4pgs.
Orthopaedic Center, Imaging Report, 5/4/07, 2pgs.
Orthopaedic Center, Myelogram Report, 4/30/07, 3pgs.
Orthopaedic Center, Office Visit Note, 4/12/07, 4pgs.
Orthopaedic Center, Operative Report, 3/30/07, 2pgs.
Orthopaedic Center, Office Visit Note, 2/14/07, 4pgs.
Orthopaedic Center, Operative Report, 1/23/07, 2 pgs.
Orthopaedic Center, Office Visit Note, 12/14/09, 4 pgs.
Orthopaedic Center, MRI Report, 12/14/06, 1 pg.

Patient clinical history [summary]

This is a female patient who was injured. She developed pain going initially towards the gluteal area in the right hip that continued to radiate towards the thighs, knees and calves as far down as the foot on the right side. The patient was treated with epidural steroid injections on 01/23/07 with 60% improvement in her symptoms. The patient underwent a second caudal epidural steroid injection on 03/20/07. It is stated that the second injection did not help as much as the first. The patient underwent lumbar CT myelogram on 05/02/07 which showed mild narrowing of the

interspace, mild/moderate broad based bulge of the disc, mild encroachment of the neural foraminas bilaterally at L4-5. At L5-S1, there was marked narrowing of the interspace. Air in the disc and moderate broad based protrusion of the disc, more marked in the midline, contacts and mildly compresses the thecal sac and the S1 nerve roots bilaterally. The patient underwent electrodiagnostic studies on 10/04/07 which were found to be normal with no evidence of lumbar radiculopathy. The patient underwent a sacroiliac joint injection on 11/13/07. a clinic note dated 11/28/07 states that the injection did not help. A clinic note dated 12/05/08 shows that the patient was prescribed Lexapro. A MRI of the lumbar spine dated 09/18/09 showed at L4-5 mild broad based bulging, more marked in the midline with mild thickening of the yellow ligament. Facet arthrosis is mild in the right more than the left. At L5-S1, the disc signal intensity and disc height are moderately diminished with a mild broad based bulging that produced mild neural foraminal and lateral and canal encroachment. In addition, there is a midline protrusion/herniation mild in size that compresses mildly the thecal sac and the nerve roots of S1 bilaterally displacing the one on the left more than the one on the right. Facet arthrosis is moderate but more marked on the left than the right. There is mild spondylosis in the canal. Clinic note dated 10/21/09 states that the patient is having a loss of bladder control. The patient also states that she remains depressed. She was recommended for a psychological evaluation before undergoing the stress and anxiety of a surgical intervention. The patient was recommended for a lumbar laminotomy and discectomy at L5 and S1. Clinic note dated 11/25/09 shows the patient was prescribed Cymbalta. There was a medical review on 12/05/09 which stated the only current prescribed medications related to the original injury would include Naprosyn and Desyrel. It was stated that the patient does not have lumbar radiculopathy and the physical exams have been too inconsistent to validate the concept of a radiculopathy. It was also stated that the patient is not a candidate for a fusion procedure, as she has no evidence of instability. The patient underwent a psychological evaluation on 12/15/09. It is stated that the previous peer review ignores the documentation in the designated doctor's diagnosis of a compensable back injury with a 5% permanent disability for her back. The psychological evaluation states that the patient did not have any prior mental illness or need for psychological treatment prior to her injury. The patient was previously evaluated by a psychiatrist in 3/08 and was diagnosed with major depression. The patient was found to be mildly depressed and mildly anxious and is having a difficult time coping with her chronic pain condition and current physical limitations. The patient was recommended for psychological treatment including 6 psychotherapy sessions and a trial of antidepressant medication. The patient was recommended to take Cymbalta which has been indicated for the treatment of neuropathic pain as well as injury-related anxiety and depression. Clinic note dated 01/22/10 states that the insurance carrier was not willing to cover the Cymbalta and the patient was recommended to use Paxil instead. Physical exam shows motor strength in upper and lower extremities are graded as 5/5. Deep tendon reflexes are normal active. Sensory exam is normal in the upper and lower extremities. Range of motion is limited to the lumbar spine in flexion/extension and lateral tilting. There is evidence of tenderness and spasm to palpation. Tiptoe and heel walking are well done. Straight-leg raise is positive on the right.

<u>Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.</u>

The medical necessity is not established for the prescribed medication Cymbalta. The psychological evaluation submitted on 12/15/09 states that the patient has mild depression and anxiety and is having a difficult time coping with her chronic pain and physical limitations. It is mentioned in the psychological evaluation that the patient has undergone a doctor-designated evaluation; however, this was not submitted for this review. The most recent clinic note dated 01/22/10 shows that the patient was prescribed Paxil. It is unknown how the patient has responded to Paxil as there were no clinic notes submitted after 01/22/10. ODG does recommend Cymbalta as an option for first line treatment for neuropathic pain; however, as the most recent physical exam submitted does not show evidence of radiculopathy and the electrodiagnostic studies were negative, the patient would not meet the criteria in ODG for the requested Cymbalta as there is no evidence that the patient has neuropathic pain.

A description and the source of the screening criteria or other clinical basis used to make the decision:

ODG, Pain Chapter
Duloxetine (Cymbalta®) Recommended as an option in first-line treatment of 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. 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 the Stress Chapter for more information and references. See 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 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)