

IRO NOTICE OF DECISION – WC



Notice of Independent Review Decision

March 5, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Tramadol/APAP 37.5-325 mg #60 1RF
Cymbalta 60 mg #30 2RF
Lunesta 3 mg #30 2RF

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

American Board of Physical Medicine and Rehabilitation
Subcertification in Pain Medicine

REVIEW OUTCOME:

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

xxxx, the claimant is a male that comes in for medication refill. He is seen for refill of Gabapentin, Cymbalta, Tizanidine, Ultracet and Lunesta. This claimant has a spinal cord stimulator with good coverage and adequate pain relief. On exam, the claimant is non tender to palpation, range of motion is full, and he is neurologically intact. Normal gait. Assessment: Long term drug use, Chronic pain syndrome, Lumbar post laminectomy syndrome, lumbar radiculitis.

12-5-13, performed a UR. Non certification for Cymbalta and Lunesta. This patient is a male who sustained a work related injury on xx/xx/xx. In a report dated 09/04/13, the patient was seen for a follow-up visit and prescription refill. The patient complained of constant lumbar spine pain that was described as aching, stabbing, and spasms quality. The patient reported that the pain was worse when walking, turning, crouching, bending, twisting, and standing and was better with medication. Available information indicated that a urine drug screen was obtained last 06/04/13 and revealed positive for Tramadol, duloxetine, and Gabapentin which were consistent with prescription medication. It was noted that the patient was a low risk for opioid abuse, diversion, or aberrant behaviors. The patient was noted to have indwelling spinal cord stimulator which provided the patient good coverage and adequate pain relief. He was no longer experiencing pain at the battery site. The patient was diagnosed with long term drug use, chronic pain syndrome, lumbar post-laminectomy syndrome and lumbar radiculitis. Cymbalta, Lunesta, Neurontin, Tizanidine, and Ultracet were refilled. This is a request for Tramadol/APAP 373-325 mg #60 1 refill, Cymbalta 60 mg #30 2 refills and Lunesta 3 mg #30 2 refills. This request is not medically necessary.

12-11-13, the claimant returns for followup visit and prescription refill. He needs a refill for Cymbalta, Gabapentin, Tizanidine, Ultracet and Lunesta. On exam, he is neurologically intact. He has full range of motion with no pain, normal strength. Plan: Medications refilled.

1-14-14, the claimant was seen for followup and medication refill. He presents with low back pain. He notes spinal cord stimulator provides good coverage and adequate relief. On exam, he has full range of motion, normal strength, SLR is negative bilaterally, sensation is decreased distally bilaterally. He has difficulty standing, SLR is negative bilaterally. The claimant was provided a refill for Cymbalta and Lunesta.

Pharmacy details.

Medication log.

2-26-14 information provided.

2-27-14 letter regarding UR.

2-27-14 Notice to Claims Eval of case assignment.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Medical records reflect a claimant with a diagnosis of chronic pain syndrome, lumbar post laminectomy syndrome, and lumbar radiculitis. He is seen regularly for medication management. He is being prescribed Tramadol, Lunesta and Cymbalta.

The most recent medical records provided for review note that the claimant has a spinal cord stimulator that provides good coverage and adequate relief. On exam, he has full range of motion, normal strength, SLR is negative bilaterally. He only has decreased sensation distally bilaterally. A particular nerve distribution not noted. He has difficulty standing, but he had normal strength. SLR is negative bilaterally. The claimant was provided a refill for Cymbalta and Lunesta.

Regarding the use of Tramadol, this medication is used as an option for pain. However, per the records provided, this claimant has basically a normal physical exam. reported that this claimant has a spinal cord stimulator with good coverage and adequate pain relief. Therefore, the use of this medication is not supported and is not medically reasonable or medically necessary.

Regarding the use of Lunesta, ODG supports the use of this medication for the treatment of insomnia. However, there is an absence in documentation noting that this claimant has insomnia related to the work injury, or any documentation regarding his sleep hygiene. Therefore, the use of this medication is not supported and is not medically reasonable or medically necessary.

Regarding the use of Cymbalta, ODG supports the use of this medication as an option in first-line treatment of neuropathic pain. However, there is an absence in documentation noting that this claimant has neuropathic pain. His physical exam does not show any evidence of neuropathy or radiculopathy. Therefore, the use of this medication is not supported and is not medically reasonable or medically necessary.

ODG 2014 Tramadol: Recommended as an option. Tramadol is a centrally acting synthetic opioid analgesic and it provides inferior analgesia compared to a combination of Hydrocodone/ acetaminophen. (Turturro, 1998) Tramadol is not classified as a controlled substance by the DEA, but it is designated schedule IV drug in 13 states. Tramadol has unreliable analgesic activity and potential side effects such as serotonin syndrome. (Ray, 2013) For more information and references, see Opioids for general guidelines, as well as specific Tramadol (Ultram® & Ultram ER®) listing for more information and references.

ODG 2014 Eszopicolone (Lunesta™) has demonstrated reduced sleep latency and sleep maintenance. ([Morin, 2007](#)) 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. ([Walsh, 2007](#)) Side effects: 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: 1-2 mg for difficulty falling asleep; 2-3 mg for sleep maintenance. The drug has a rapid onset of action. ([Ramakrishnan, 2007](#))

ODG 2014 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](#)) An FDA panel concluded that Cymbalta was effective in treating chronic low back pain, and they voted in favor of Eli Lilly's request to broaden the indication to include the treatment of chronic pain. ([FDA, 2010](#)) On November 4, 2010, the FDA approved duloxetine HCl delayed-release

capsules (Cymbalta; Eli Lilly and Co) for the once-daily treatment of chronic musculoskeletal pain. Regulatory approval followed a positive vote regarding the use of duloxetine to treat chronic low back pain, but the committee did not express the same confidence in the drug's usefulness as a treatment for osteoarthritis. Despite this, duloxetine has been approved for both chronic low back pain and osteoarthritis. The recommended dose is 60 mg daily. Duloxetine delayed-release capsules previously were approved for the treatment of major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathic pain, and fibromyalgia. ([FDA2, 2010](#))

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- INTERQUAL CRITERIA**
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**

- MILLIMAN CARE GUIDELINES**
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- TEXAS TACADA GUIDELINES**
- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION):**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**