

AccuReview
An Independent Review Organization
Phone (903) 749-4271
Fax (888) 492-8305

Notice of Independent Review Decision

DATE OF REVIEW: January 9, 2012 Amended January 12, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Outpatient office visit on 10/24/11 and medications including, Cymbalta (billed 07/21/11), Lansoprazole [Prevacid] (billed 06/16/11) and Neurontin (billed 07/24/11).

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

This physician is Board Certified Physical Medicine and Rehabilitation with over 15 years of experience.

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 or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

05-26-11: RME by MD

06-07-11: Letter of Intent to Endorse RME Report Recommendations

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant was injured on xx/xx/xx. According to the very limited records he is status post cervical surgery with a multiple level fusion.

05-26-11: RME by MD. Dr. reported that he originally performed an IME on the claimant. The current medications were listed as Tylenol, six tablets per day for pain; as well as Neurontin, dose unknown at bedtime; and Cymbalta 30 milligrams, one in the morning and two at bedtime. He also used Prevacid due to stomach trouble which the claimant believed was caused by medication use over the years. On physical examination Spurling's test was negative/normal. Biceps and triceps reflexes were 2/4 and symmetric, and brachioradialis was trace bilaterally. There was generalized decreased sensation over the right upper extremity. He had make-break weakness in the shoulder. Interossei were very weak in the bilateral hands. He had poor grip strength bilaterally with inadequate effort exerted by the claimant. Dr. reported that the claimant had the same generalized type findings that he had at the time of his last evaluation. There was no evidence of radiculopathy. He had nonspecific upper back and arm pain. Dr. stated that would be appropriately called fibromyalgia and a somatoform disorder with prominent pain features, which would not be work-related conditions. Dr. went on to state that even if the claimant was suffering from a work-related conditions, he was functioning below the expected functional level. Dr. responded to specific questions with the following opinions: 1. It continues to be my opinion that the claimant suffers from a non-work-related condition which has been inappropriately attributed to the alleged compensable injuries. As such then, he does not require ongoing treatment for the alleged compensable injuries. Any treatment that the claimant requires should be provided outside of the workers' comp system. 2. I see no indication for any surgery here related to the date of injury in question. Certainly there is no indication for any implantable device. Implantable devices such as a spinal cord stimulator or pain pumps are not appropriately used in the treatment of nonspecific chronic pain. 3. There is no indication for any sort of injections here. The claimant himself reports that injections are not helpful and actually cause more problems than they resolve. 4. I see no indication for any ongoing formal treatment. All reasonable amounts of therapy have been exhausted here. ODG does not support durable medical equipment such as Tens Unit. There is no indication for any diagnostics. I see no indication for behavioral health or pain management related to the alleged compensable injuries. There is no indication for acupuncture or hypnosis. 5. I see no indication for these medications (Prevacid, Tylenol, Cymbalta and Gabapentin) related to the date of injury in question. If the claimant requires Tylenol, he can obtain it over the counter. I do not believe that his chronic pain syndrome is work-related. His use of Tylenol then would not be appropriate under the workers' comp system. I find no evidence of a work-related stomach problem. As such then, the claimant's ongoing use of Prevacid is unrelated to the alleged

compensable injuries. In relation to Cymbalta, this is not a pain medication that is appropriately used, other than in cases of diabetic peripheral neuropathy. There is no evidence that it helps the wide variety of nonspecific chronic pain syndromes that are seen. There is no indication here that the claimant has a work-related psychological condition that requires the use of Cymbalta. Even if this claimant was using Cymbalta appropriately for work-related chronic pain, I find no evidence that his medication has been efficacious here. The claimant then should be weaned off of his Cymbalta, which would take four to six weeks. In regards to the use of Gabapentin, I see no evidence that its use is effective here. The claimant is taking one per day. The Gabapentin can be stopped without weaning. 6. I see no indication for additional office visits once the claimant is weaned off of his medication. There is no indication for any referrals. 7. I believe the claimant is being treated for disease of life from which he is suffering, not the effects of the alleged compensable injuries. 8. Again, ODG does not support the use of treatment which has not proven to be effective. In this case, then, there is no indication for ongoing treatment according to ODG.

06-07-11: Letter of Intent to Endorse RME Report Recommendations. According to this documentation the following disputes are on file regarding this claim: Chest pain; Pulmonary condition; Pleuritic areas of lungs; Peripheral Neuropathy; Carpal tunnel/bilateral; Bilateral shoulders; Fibromyalgia; Bilateral elbows; Borderline diabetes or any glucose abnormal condition; Renal stones or any genitourinary conditions; Gastrointestinal disorders, including reflux and irritable bowel syndrome, requiring proton pump inhibitor medications; New or exacerbation of the previous injury as a result of a intervening accident that occurred on xx/xx/xx at work while moving a battery; as a result of the new injury the injured worker reports low back pain, with his legs hurting and neck pain. Carrier denies that the new low back injury and exacerbation to cervical is related to the compensable injury. Diagnosis was possible lumbar and thoracic discogenic changes, carrier denies this is related to the compensable injury 8/18/92; Tennis elbow, carpal tunnel, irritable bowel, acid reflux, borderline diabetes, cholecystectomy and kidney stones: [this was reported on a report by Dr. on 2/19/09]; headaches of any description; sleep disorders; including insomnia; psychiatric disorders; including anxiety, depression, nervousness. Per the letter, no further office visits would be funded as of 8/2/11, following a weaning time line. Regarding the prescriptive medications A] Gabapentin [Neurontin] had not been funded since Feb 2011, B] Tylenol/Acetaminophen would not be funded. The last funding was 6/28/11 and there would be no further funding as it does not require a prescription, C] Lansoprazole [Prevacid] was last filled 5/17/11 and there would be no further funding, D] Cymbalta was last funded on 5/9/11. Since this medication requires a 4-6 weaning time frame, the carrier would allow the June and July fill of Cymbalta. As of 7/12/11, there would be no further funding of the Cymbalta.

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

Denial of 10/24/11 office visit and medications including Cymbalta, Prevacid and Neurontin is upheld/agreed upon. The 5/26/11 RME and 6/7/11 Letter to Endorse RME recommendations were the only clinical documents submitted for review, despite request for records being sent to the provider. Therefore, there is a lack of information to support the office visit, since it is uncertain as to what the visit pertained, and there is no clinical information submitted as to what the medications are prescribed for, their actual use, their effectiveness or their side effects.

Amended Report: I have been asked to explain why I diverted from using ODG when reviewing this case. As stated above, I only received two documents of medical records, an RME completed by MD on 5/26/11 and the 6/7/11 Letter to Endorse the RME recommendations. As Dr. had previously performed an RME on this claimant, no initial details were supplied of how the claimant was injured and what the claimant's injuries were as a result of the incident. I was only able to gather that the claimant had undergone a multilevel cervical fusion. I do not have any other documentation as to what other treatments had been provided to the claimant. I have no medical documentation as to what the prescribed medications are prescribed for, their actual use, their effectiveness or their side effects. It is difficult to site the ODG with the lack of clinical information. However, I will attempt to include the ODG below.

Per the ODG, Cymbalta has been approved for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy. Without any clinical documentation of the claimant's current symptoms and diagnosis, it cannot be determined utilizing ODG if the medication is appropriate and is therefore denied.

Per the ODG, Neurontin (Gabapentin) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. Again, without any clinical documentation of the claimant's current symptoms or diagnosis, it cannot be determined utilizing ODG if the medication is appropriate. Diabetic painful neuropathy would not be a result of a work-related injury. Therefore this medication is denied.

Per the ODG, Prevacid is recommended for patients at risk for gastrointestinal events. I do not believe there would be any work-related stomach problems and therefore, this medication would not meet ODG criteria and would be denied.

There was no documentation provided that would indicate the reason for the office visit. I can only assume it was for the maintenance of the above medications. If this was the case and the medications have been denied, then the office visit would not be medically necessary.

ODG:

<p>Duloxetine (Cymbalta®)</p>	<p>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)</p>
<p>Gabapentin (Neurontin®)</p>	<p>Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Gabapentin listing for more information and references.</p>
<p>Proton pump inhibitors (PPIs)</p>	<p>Recommended for patients at risk for gastrointestinal events. See NSAIDs, GI symptoms & cardiovascular risk. Prilosec® (omeprazole), Prevacid® (lansoprazole) and Nexium® (esomeprazole magnesium) are PPIs. Omeprazole provides a statistically significantly greater acid control than lansoprazole. (Miner, 2010) Healing doses of PPIs are more effective than all other therapies, although there is</p>

	<p>an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. For many people, Prilosec is more affordable than Nexium. Nexium is not available in a generic (as is Prilosec). Also, Prilosec is available as an over-the-counter product (Prilosec OTC®), while Nexium is not. (Donnellan, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)</p>
--	--

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)**