MEDICAL CONTESTED CASE HEARING NO 12073
M5-11-35266-01

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUES

A contested case hearing was held on January 26, 2012 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization that Claimant is not entitled to reimbursement of $115.02 for Cymbalta prescribed by Dr. B on April 20, 2011 for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by JO, ombudsman.
Respondent/Carrier appeared and was represented by SC, attorney.

BACKGROUND INFORMATION

Claimant, an oncology nurse, sustained injuries to her cervical and lumbar spine on (Date of Injury) when she was assisting a patient into a chair. The patient grabbed Claimant around the neck because he thought she was going to lift him up and, in doing so, he pulled Claimant down by her neck resulting in injuries to her spine. Claimant underwent a cervical fusion and two lumbar surgeries. She also received physical therapy. Claimant is currently controlling her symptoms with medications.

Claimant began treating with Dr. B on April 20, 2011. Dr. B took a detailed history, performed a physical examination, and prescribed medications. Dr. B specifically prescribed Tylenol and Cymbalta. Claimant testified, and the medical records also reflect, that she had been taking both medications for several years prior to her visit with Dr. B. Dr. B's medical report indicates that since surgery is no longer an option that he wanted Claimant to see a pain management specialist. In the meantime, he stated he would prescribe several medications including Tylenol Extra Strength and Celebrex.

Claimant presented her prescriptions to the pharmacy and the Carrier did not authorize the Celebrex and Tylenol. Claimant paid for both medications and submitted her request for reimbursement to the Carrier. The Carrier denied payment. The Carrier based its denial on the report of orthopedic surgeon, Dr. A, who performed a required medical examination on August

3, 2010. Dr. A was asked to answer specific questions concerning reasonable and necessary medical treatment. Dr. A was specifically asked if Claimant needed to continue taking Celebrex, Gabapentin, Cymbalta, and Pantoprazole. Dr. A opined that the prescribed medications were not reasonable, necessary, or related to the compensable injury.

Claimant appealed the Carrier's denial of her medications and an IRO was appointed to perform a retrospective review of the medical necessity of the reimbursement of the medications Cymbalta and Tylenol. The IRO physician, a board certified orthopedic surgeon, determined that there was a clear clinical indications for the Tylenol but not for the Cymbalta.

Upon receiving an unfavorable decision from the IRO, Claimant requested a Medical Contested Case Hearing to resolve the dispute over the medical necessity of Cymbalta and to seek reimbursement for the money she paid for her prescription.

DISCUSSION

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011 (22a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence based medicine or, if evidence based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is available. Evidence based medicine is further defined in Texas Labor Code Section 401.011 (18a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines in making decisions about the care of individual patients. The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. (Texas Labor Code Section 413.011(e).) Medical services consistent with the medical policies and fee guidelines adopted by the Commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308 (t), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division is considered

parties to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

With regard to Cymbalta the ODG provides as follows:

> 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)

The IRO physician reviewer relied on medical judgment, clinical experience and expertise in accordance with accepted medical standards and the ODG. All were used as the screening criteria and clinical basis for making the decision to overturn Carrier's denial of Tylenol and uphold Carrier's denial of the Cymbalta. As it relates to the Cymbalta, the physician reviewer stated:

> As noted in the Division mandated Official Disability Guidelines, Cymbalta is 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). Although, in this case there is not a neuropathic pain situation and there is no diabetic neuropathy, anxiety disorder or depression. Therefore, this would not be clinically indicated.

To overcome the IRO decision, Claimant offered her testimony and the medical records of the various providers that have treated her condition. Claimant testified that has been prescribed Cymbalta for more than ten years and that the medication is necessary to treat her back pain. Claimant testified that the medication reduces her pain level, helps her to focus, and allows her to live with her problems. Claimant also presented medical reports from Dr. B (2), Dr. B, and Dr. L to support her position.

Dr. B (2) performed a required medical examination on August 26, 2008 and he opined that Claimant's medications, including Cymbalta, were medically reasonable and necessary. Dr. B (2) went on to state that Claimant would require treatment indefinitely.

Dr. B responded to the IRO decision in a letter dated July 5, 2011. Dr. B states that he believes Claimant should continue the medication regimen that she was placed on prior to seeing him. Dr. B notes that Claimant's medications are not the types of medications that are addictive or that are

abused. Dr. B provides general reasons why Claimant's medication regimen should be continued, but does not specifically address the medical necessity of Cymbalta.

Claimant was referred to pain management specialist, Dr. L, by Dr. B. Dr. L examined Claimant on December 1, 2011. In his report, Dr. L stated that Claimant has been able to function very well with the use of non-addictive medications, Cymbalta and gabapentin. Therefore, he believes it is in her best interest to continue these medications. Dr. L states that these medications provide Claimant with the most comfort and the least suffering and to deny these medications could cause the Claimant additional suffering.

Claimant's testimony was credible and the medical evidence was considered. However, the Petitioner/Claimant has not shown by a preponderance of evidence-based medical evidence that the requested medication, Cymbalta, is health care reasonably required for the compensable injury. Therefore, Claimant is also not entitled to reimbursement in the amount of $115.02 for Cymbalta prescribed by Dr. B on April 20, 2011.

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

   A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

   B. On (Date of Injury), Claimant was the employee of (Employer), Employer.

   C. Claimant sustained a compensable injury on (Date of Injury).

   D. The Independent Review Organization determined that Claimant is not entitled to reimbursement for Cymbalta for the compensable injury of (Date of Injury).

2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. Cymbalta is not health care reasonably required for the compensable injury of (Date of Injury).

4. The preponderance of the evidence is not contrary to the decision of the IRO rendered on July 15, 2011 that Petitioner/Claimant is not entitled to reimbursement of the medication Cymbalta for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.

2. Venue is proper in the (City) Field Office.

3. The preponderance of the evidence is not contrary to the decision of the IRO that Cymbalta is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to reimbursement in the amount of $115.02 for Cymbalta prescribed by Dr. B on April 20, 2011 for the compensable injury of (Date of Injury).

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **CHARTER OAK FIRE INSURANCE COMPANY** and the name and address of its registered agent for service of process is:

CORPORATION SERVICE COMPANY
d/b/a CSC – LAWYERS INCORPORATING SERVICE CO.
211 EAST 7TH STREET, STE. 620
AUSTIN, TX 78701-3218

Signed this 3rd day of February, 2012.

Jacquelyn Coleman
Hearing Officer