

MEDICAL CONTESTED CASE HEARING NO. 13098

**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 May 22, 2013 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the claimant is not entitled to Diclofenac Sodium 75mg and Lyrica 100mg, for the compensable injury of (Date of Injury)?

**PARTIES PRESENT**

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

**BACKGROUND INFORMATION**

The claimant sought reimbursement from the carrier for her out-of-pocket expenses for Diclofenac Sodium 75mg and Lyrica 100mg. Diclofenac Sodium 75mg is an NSAID (non-steroidal anti-inflammatory drug). Lyrica 100mg is an AED (anti-epilepsy drug). The claimant was taking both medications for pain. The carrier denied the request for reimbursement twice, and the claimant appealed. An Independent Review Organization (IRO) was appointed to settle the dispute. The IRO determined that the medications were not medically necessary. The IRO decision indicates that the doctor who conducted the review for the IRO was board-certified by the American Boards of Physical Medicine and Rehabilitation and Pain Management. The decision also indicates that the doctor relied in part on the treatment portion of the Official Disability Guidelines (ODG) in conducting the review.

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. Section 401.011(22-a) defines health care reasonably required 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 (A) evidence-based medicine; or (B) if that evidence is not available, generally accepted standards of medical practice recognized in the medical community."

Evidence-based medicine is medicine that is firmly supported by 1) credible scientific studies, including peer-reviewed medical literature and other current, scientifically based texts, and/or 2)

treatment and practice guidelines, such as the treatment portion of the Official Disability Guidelines (ODG). **Texas Labor Code Section 401.011 (18-a).**

The Division of Workers' Compensation has adopted treatment guidelines under Division Rule 137.100. That rule requires that health care providers provide treatment in accordance with the current edition of the ODG, and treatment provided pursuant to those guidelines is presumed to be health care reasonably required as mandated by the above-referenced sections of the Texas Labor Code. The initial inquiry in any dispute regarding medical necessity is whether the proposed care is consistent with the ODG.

With regard to the NSAID's (non-steroidal anti-inflammatory drugs), under Pain (Chronic), the ODG reads as follows:

*Osteoarthritis (including knee and hip):* Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008)

*Back Pain - Acute low back pain & acute exacerbations of chronic pain:* Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007)

*Back Pain - Chronic low back pain:* Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications.

*Neuropathic pain:* There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006)

See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) Revised AGS practice guidelines on the management of persistent pain (including noncancer-related pain) in the elderly recommend that patients avoid NSAIDs and consider the use of low-dose opioid therapy instead, because the risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, usually outweigh the benefits. (AGS, 2009)

With regard to the AED's (anti-epilepsy drugs), under Pain (Chronic), the ODG reads as follows:

Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants.

Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). (Gilron, 2006) (Wolfe, 2004) (Washington, 2005) (ICSI, 2005) (Wiffen-Cochrane, 2005) (Attal, 2006) (Wiffen-Cochrane, 2007) (Gilron, 2007) (ICSI, 2007) (Finnerup, 2007) There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. (Attal, 2006) The choice of specific agents reviewed below will depend on the

balance between effectiveness and adverse reactions. See also specific drug listings below: Gabapentin (Neurontin®); Pregabalin (Lyrica®); Lamotrigine (Lamictal®); Carbamazepine (Tegretol®); Oxcarbazepine (Trileptal®); Phenytoin (Dilantin®); Topiramate (Topamax®); Levetiracetam (Keppra®); Zonisamide (Zonegran®); & Tiagabine (Gabitril®).

*Outcomes:* A “good” response to the use of AEDs has been defined as a 50% reduction in pain and a “moderate” response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the “trigger” for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. AEDs are associated with teratogenicity, so they must be used with caution in woman of childbearing age. Preconception counseling is recommended for anticonvulsants (due to reductions in the efficacy of birth control pills). (Clinical Pharmacology, 2008) Manufacturers of antiepileptic drugs will need to add a warning to their labeling indicating that use of the drugs increases risk for suicidal thoughts and behaviors, according to an FDA Alert issued December 16. (FDA MedWatch, 2008)

*Specifically studied disease states:*

*Painful polyneuropathy:* AEDs are recommended on a trial basis (gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy (with diabetic polyneuropathy being the most common example). The other first-line options are a tri-cyclic antidepressant (if tolerated by the patient), or a SNRI antidepressant (such as duloxetine). (Attal, 2006) (Jensen, 2006)

*Postherpetic neuralgia:* Gabapentin and pregabalin are recommended. (Attal, 2006) (Backonja, 2004)

*Central pain:* There are so few trials (with such small sample size) that treatment is generally based on that recommended for peripheral neuropathy, with gabapentin and pregabalin recommended. Lamotrigine has been found to be effective for central post-stroke pain (see below for specific drugs), and gabapentin has also been found to be effective. (Backonja, 2004)

*Acute pain:* Not indicated due to lack of evidence.

*Chronic non-specific axial low back pain:* A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. (Chou, 2007) There is one randomized controlled study that has investigated topiramate for chronic low back pain. (Muehlbacher, 2006) This study specifically stated that there were no other studies to evaluate the use of this medication for this condition. Patients in this study were excluded if they were taking opioids. No patient had undergone back surgery. In terms of the Oswestry low back pain questionnaire scale, the differences in the placebo group and treatment group were significant, although the mean score in both groups remained  $\geq 34$ . Reduction in pain rating index appeared to be correlated with weight reduction. See Topiramate below. The authors felt additional research was required to see if the results could be replicated and how long-lasting benefits were. There are no other articles available that evaluate the use of other anti-epilepsy drugs in the treatment of chronic non-specific, non-neuropathic axial low back pain.

*Treatment of pain associated with osteoarthritis of the hip:* Not indicated

*Spinal cord injury:* Gabapentin is recommended for chronic neuropathic pain. (Levendoglu, 2004)

*CRPS:* Gabapentin has been recommended (Serpell, 2002)

*Fibromyalgia:* Gabapentin and pregabalin have been found to be safe and efficacious to treat pain and other symptoms. (Arnold, 2007) (Crofford, 2005) Pregabalin is FDA approved for fibromyalgia.

*Lumbar spinal stenosis:* Gabapentin produced statistically significant improvement in walking distance, decrease in pain with movement and sensory deficit in a pilot study. (Yaksi, 2007)

*Myofascial pain:* Not recommended. There is a lack of evidence to demonstrate that AEDs significantly reduce the level of myofascial or acute musculoskeletal pain, or other sources of somatic pain. (Wiffen-Cochrane, 2005) (Washington, 2005)

*Postop pain:* AEDs may also be an option for postoperative pain, resulting in decreased opioid consumption. (Peng, 2007) (Buvanendran, 2007)

To overcome an IRO decision which denies treatment (including medications), a claimant must do *one* of the following:

- 1) Show that the requested treatment is consistent with the criteria set out by the Official Disability Guidelines (ODG);
- 2) Present evidence-based medicine that is more persuasive than the ODG. In other words, a claimant must present documentation or testimony that is based on evidence-based medicine. That documentation or testimony must show that the requested treatment is likely to be effective; or
- 3) Show that the requested treatment is not addressed by the ODG. In such a case, a claimant must show that the requested treatment is supported by other evidence-based medicine, or if there is no evidence-based medicine on point, a claimant must show that the requested treatment meets the generally accepted standards of medical practice recognized in the medical community.

The claimant argued that the decision of the IRO was wrong. She asserted that, given the nature of her injury and the resulting long-term pain, the prescribed medications were reasonable and necessary. To support her assertion, the claimant presented medical records which documented her medical condition and past treatment. She also presented testimony from her doctor, Dr. A, M.D. Dr. A testified by telephone. Dr. A testified that, based on his education, training, and experience, the prescribed medications were medically reasonable and necessary.

The claimant, however, did not do any of the following:

- 1) Show that the requested treatment is consistent with the criteria set out by the Official Disability Guidelines (ODG);
- 2) Present evidence-based medicine that is more persuasive than the ODG; or
- 3) Show that the requested treatment is not addressed by the ODG and, therefore, must be judged based on other evidence-based medicine or based on the generally accepted standards of medical practice recognized in the medical community

As a result, the claimant failed to meet her burden of proof.

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), the Claimant was the employee of (Employer), Employer.
  - C. On (Date of Injury), the Claimant sustained a compensable injury.
  - D. The IRO determined that the claimant should have not have Diclofenac Sodium 75 mg and Lyrica 100 mg, for the compensable injury of (Date of Injury).
2. Carrier delivered to Claimant/Petitioner 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. Diclofenac Sodium 75 mg and Lyrica 100 mg are not health care reasonably required 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 Diclofenac Sodium 75 mg and Lyrica 100 mg are not health care reasonably required for the compensable injury of (Date of Injury).

## **DECISION**

Claimant is not entitled to Diclofenac Sodium 75 mg and Lyrica 100 mg 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 **TRAVELERS INDEMNITY COMPANY OF CONNECTICUT** and the name and address of its registered agent for service of process is

**CORPORATION SERVICE CO.  
D/B/A CSC – LAWYERS INCORPORATING SERVICE COMPANY  
211 EAST 7TH STREET, STE. 620  
AUSTIN, TEXAS 78701-3218**

Signed this 30th day of May, 2013

Carlos Cerrato  
Hearing Officer