MEDICAL CONTESTED CASE HEARING NO. 13014
M5-12-40976-01

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.

ISSUE

A medical contested case hearing was held on October 25, 2012 to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Claimant is not entitled to 30 tablets of Topiramate 200 MG for date of service of February 9, 2012 for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Claimant/Petitioner (hereinafter Claimant) appeared and was assisted by BO, ombudsman. Carrier/Respondent (hereinafter Carrier) appeared and was represented by RL, attorney.

EVIDENCE PRESENTED

The following witnesses testified:

> For Claimant: Claimant.
>
> For Carrier: None.

The following exhibits were admitted into evidence:

> Hearing Officer's Exhibits HO-1A, HO-1B, HO-2, HO-3, and HO-4.
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> Claimant's Exhibits C-1 through C-5.
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> Carrier's Exhibits CR-A through CR-C.

BACKGROUND INFORMATION

The evidence presented in the hearing revealed that Claimant sustained a compensable injury to include her low back on (Date of Injury) following a fall while trying to step out of a stalled office elevator. The evidence presented indicates that Claimant has received conservative

treatment for the compensable injury, including medications, physical therapy, epidural steroid injections (ESIs), and the placement of a spinal cord stimulator that was later removed. The evidence also indicated that Claimant has been prescribed Topiramate (also known as "Topamax"), an anti-convulsant/anti-epilepsy medication, for pain control since 2002. The retrospective medical necessity of 30 tablets of a 200 MG dosage of this medication was denied after an initial review by a Utilization Review Agent (URA) and this denial was upheld by a second URA following a request for reconsideration. Claimant then requested a review by an Independent Review Organization (IRO).

The IRO reviewer upheld the denial of the medication based on the Official Disability Guidelines (ODG) and the reviewer's medical judgment, clinical experience and expertise in accordance with accepted medical standards. The IRO reviewer cited pertinent excerpts from the ODG, which recommend the medication for "neuropathic" pain (i.e., "pain initiated or caused by a primary lesion or dysfunction of the nervous system." *See* Carrier's Exhibit CR-C, p. 9). The ODG do not recommend this type of medication for acute "nociceptive" pain (i.e., "pain caused by activation of nociceptors, which are sensory neurons found throughout the body. A nociceptor is 'a receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged'". *See* Carrier's Exhibit CR-C, p. 9). The IRO reviewer did not find that Claimant had any evidence of neuropathic pain, or a history of epilepsy or migraine headaches for which the medication could be used. Though the IRO reviewer observed that Claimant has diabetes, the reviewer did not find evidence that the medication was prescribed for complications stemming from that condition, such as painful polyneuropathy. Claimant testified in the hearing that she actually began taking Topiramate four years before she was diagnosed with diabetes. Claimant appealed the unfavorable decision of the IRO to this medical contested case hearing (MCCH).

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. 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 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 are 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 Topiramate, the ODG Low Back Chapter provides, as follows:

> Under study. 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. 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 ≥ 34. Reduction in pain rating index appeared to be correlated with weight reduction. Weight loss was significantly more pronounced in the group treated with topiramate than in those treated with placebo. 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. See the Pain Chapter, Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Topiramate listing.

The ODG Pain Chapter provides, in pertinent part, as follows concerning Topiramate in the section related to anti-epilepsy drugs:

> 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: (also see below for specific drugs)

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 ≥ 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.

Other Antiepileptic Drugs

Topiramate (Topamax®, generic available) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard. (Rosenstock, 2007)

The decision of the IRO reviewer, as noted above, was largely based on the ODG. Carrier relied on the URA and IRO decisions, as well as the evidence-based medical studies provided as part of its evidence, to argue that anti-convulsant/anti-epileptic medication, such as Topiramate, is not medically necessary treatment for Claimant's compensable injury. Claimant, as the party challenging the IRO decision, has the burden of proof to overcome the IRO decision by a preponderance of evidence-based medical evidence. Evidence-based medical evidence entails the opinion of a qualified expert that has some basis in evidence-based medicine. Expert evidence is required in all medical necessity disputes and, though Claimant put forth highly credible testimony in the hearing, her lay testimony is not probative on questions requiring expert evidence, such as the inquiry into the medical necessity of the medication at issue. The records provided by Claimant in support of her position, including the reports of the Carrier-selected independent medical examination (IME) doctor, MD, M.D., and treating physician, VR, M.D., were considered, but those records did not provide an adequate explanation, with a sufficient

foundation in evidence-based medicine, to establish the medical necessity of the 200 MG of Topiramate at issue for her compensable injury of (Date of Injury). As Claimant did not meet her burden of proof, a preponderance of the evidence is held not to be contrary to the decision of the IRO that 30 tablets of Topiramate 200 MG for date of service of February 9, 2012 is not health care reasonably required for the compensable injury of (Date of Injury).

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), and sustained a compensable injury.

   C. On (Date of Injury), Employer provided workers' compensation insurance coverage through Insurance Company of North America.

   D. The Independent Review Organization (IRO) determined that the health care at issue in this case was not reasonably required 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. 30 tablets of Topiramate 200 MG for date of service of February 9, 2012 is 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 30 tablets of Topiramate 200 MG for date of service of February 9, 2012 is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to 30 tablets of Topiramate 200 MG for date of service of February 9, 2012 for the compensable injury of (Date of Injury).

ORDER

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

The true corporate name of the insurance carrier is **INSURANCE COMPANY OF NORTH AMERICA** and the name and address of its registered agent for service of process is:

C T CORPORATION SYSTEM
350 NORTH ST PAUL STREET
DALLAS, TEXAS 75201

Signed this 29th day of October, 2012.

Jennifer Hopens
Hearing Officer