MEDICAL CONTESTED CASE HEARING NO. 10178
M6-10-25839-01

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 May 20, 2010 to decide the following disputed issues:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that the Claimant is not entitled to Neurontin 600mg, Percocet 10-325mg, and Valium 10mg for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant (Hereinafter Claimant.) appeared and was assisted by LS, ombudsman. Respondent/Carrier (Hereinafter Carrier.) appeared and was represented by RS, attorney.

BACKGROUND INFORMATION

The Claimant sustained a compensable injury on _____ from repetitive trauma at work. On July 18, 1996 the Claimant had a cervical fusion at C6-C7 and on November 21, 1997 a right carpal tunnel release. Neither of these operations helped the Claimant with her pain, and she requests that her medications be approved. The Claimant stated she has been taking Neurontin for pain for three or four years, taking two per day. The Claimant stated she has been taking Percocet for pain for three years, taking two per day. The Claimant stated that she has been taking Valium as a sleep aid for three months, taking one before going to bed. The Claimant's husband testified to explain the differences in the Claimant when she was taking the medications as opposed to when she was not taking the medications.

On January 27, 2010, a utilization review doctor, Dr. M, an internal medicine/occupational medicine doctor, denied the certification of the above listed medications. On February 12, 2010, a reconsideration utilization review doctor, Dr. B, an anesthesiologist, also denied the certification of the above listed medications.

An IRO reviewer (board certified in anesthesiology, certified in pain medicine, and chief of anesthesiology at a local hospital) reviewed the records and upheld the adverse determinations of the utilization review doctors. The IRO doctor noted that the Official Disability Guidelines (*ODG*) do not support the chronic use of the requested medications. Noting that the submitted medical records did not substantiate a diagnosis of neuropathic pain, the IRO reviewer stated the presence of tenderness indicates nociceptive pain. The IRO reviewer stated Neurontin is indicated only for neuropathic pain. The use of diazepam (Valium) or other benzodiazepines is not recommended for an extended period of time because the patient may develop a tolerance and face serious withdrawal symptoms if the medicine is discontinued. As to the Percocet several times per day, the IRO reviewer stated that generally, longer acting opioids are

recommended to the treatment of chronic pain. In addition, the IRO reviewer stated there was no indication that standard protocols for chronic opioid administration were being followed.

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, and 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."

ODG

The initial inquiry, therefore, in any dispute regarding medical necessity, is whether the proposed care is consistent with the *ODG*. The *ODG* allows for the use of all of the medications requested, with specific limitations and requires documentation of improved function and activity as well as efficacy in pain control for use of the medications.

The *ODG* Treatment Guidelines for chronic pain medications discuss the requested medications as follows:

> ***Medications for Sub-Acute and Chronic Pain***
>
> Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of

the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices listed separately (not all recommended).

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)

Gabapentin (Neurontin®, Gabarone™, generic available) 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. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study.
Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007)

Opioids for Chronic Pain

Recommendations for general conditions:
- *Neuropathic pain:* Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See Opioids for neuropathic pain.
- *Chronic back pain*: Appears to be efficacious but limited for short-term pain relief. Long-term efficacy is unclear (>16 weeks), and there is also limited evidence for the use of opioids for chronic low back pain. (Martell-*Annals*, 2007) Failure to respond to a time-limited course of opioids has led to the suggestion of reassement and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-*Annals*, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007)
- *Headaches*: not recommended, in particular, due to the risk of medication overuse headache. (Lake, 2008) (Olesen, 2006) See Medication overuse headache.
- *Osteoarthritis*: Not recommended as a first-line therapy. Recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or NSAIDs when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Under study for long-term use as there is a lack of evidence to allow for a treatment recommendation. If used on

a long-term basis, the criteria for use of opioids should be followed. See Opioids for osteoarthritis for citations.

- *Nociceptive pain:* Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury, with the most common example being pain secondary to cancer).
- *Mechanical and compressive etiologies*: rarely beneficial.

Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, **analgesic** treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (≤70 days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. (Ballantyne, 2006) (Furlan, 2006) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). (Kalso, 2004) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-*Annals*, 2007) Current studies suggest that the "upper limit of normal" for opioids prior to evaluation with a pain specialist for the need for possible continuation of treatment, escalation of dose, or possible weaning, is in a range from 120-180 mg morphine equivalents a day. (Ballantyne, 2006) (AMDG, 2007)

There are several proposed guidelines for the use of opioids for chronic non-malignant pain, but these have not been evaluated in clinical practice, and selection of the patient that will best respond to this treatment modality remains difficult. (Nicholas, 2006) (Stein, 2000) One of the most recent of these guidelines is the Agency Medical Director's Group (AMDG) Guidelines from Washington State. This guideline includes an opioid dosing calculator. (AMDG, 2007)

Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. (Nicholas, 2006) (Ballantyne, 2006) A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. (Eriksen, 2006)

Tolerance and addiction: Opioid tolerance develops with the repeated use of opioids and brings about the need to increase the dose and may lead to sensitization. It is now clear that analgesia may not occur with open-ended

escalation of opioids. It has also become apparent that analgesia is not always sustained over time, and that pain may be improved with weaning of opioids. (Ballantyne, 2006) (Ballantyne, 2003) See Substance abuse (tolerance, dependence, addiction).

Behavior reinforcement: A major concern in the use of opioids has been that a focus on this treatment without coordination with other modalities, such as psychosocial or behavioral therapy, may simply reinforce pain-related behavior, ultimately undermining rehabilitation that has been targeted at functional restoration. (Ontario, 2000) It has been shown that pain behavior can be reinforced by the prescribing of opioids, generally on an unintentional basis by the patient. (Fordyce, 1991)

Overall treatment suggestions: Current guidelines suggest the following:

- A trial of opioids as a first step in treatment, and the steps involved are outlined in the Criteria for Use of Opioids. The trial includes an initiation phase that involves selection of the opioid and initial dose. (VA/DoD, 2003)
- There is then a titration phase that includes dose adjustment. At this phase it may be determined that opioids are not achieving the desired outcomes, and they should be discontinued.
- The final stage is the maintenance phase. If pain worsens during this phase the differential to evaluate includes disease progression, increased activity, and/or new or increased pre-existing psychosocial factors that influence pain. In addition, the patient may develop hyperalgesia, tolerance, dependence or actual addiction.

(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) See Substance abuse (tolerance, dependence, addiction). See also Implantable pumps for narcotics. See also Opioids in the Low Back Chapter. See Criteria for Use of Opioids.

Oxycodone/acetaminophen *(Percocet®; generic available): Side Effects:* See opioid side effects and acetaminophen. *Analgesic dose:* Dosage based on oxycodone content and should be administered every 4 to 6 hours as needed for pain. Initially 2.5 to 5 mg PO every 4 to 6 hours prn. Note: Maximum daily dose is based on acetaminophen content (Maximum 4000mg/day). For more severe pain the dose (based on oxycodone) is 10-30mg every 4 to 6 hours prn pain. Dose should be reduced in patients with sever liver disease.

Benzodiazepine (Valium)

Not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to

lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. (Baillargeon, 2003) (Ashton, 2005) (Dickinson, 2009) (Lader, 2009) See also Anxiety medications in chronic pain; & Insomnia treatment.

Other Evidence Based Medicine

When weighing medical evidence, the hearing officer must first determine whether the doctor giving the expert opinion is qualified to offer it, but also, the hearing officer must determine whether the opinion is relevant to the issues in the case and whether the opinion is based upon a reliable foundation. An expert's bald assurance of validity is not enough. *See* ***Black v. Food Lion, Inc.***, 171 F.3rd 308 (5th Cir. 1999); ***E.I. Du Pont De Nemours and Company, Inc. v. Robinson***, 923 S.W.2d 5 549 (Tex. 1995). When determining reliability, the hearing officer must consider the evidence in terms of (1) general acceptance of the theory and technique by the relevant scientific community; (2) the expert's qualifications; (3) the existence of literature supporting or rejecting the theory; (4) the technique's potential rate of error; (5) the availability of other experts to test and evaluate the technique; (6) the clarity with which the theory or technique can be explained to the trial court; and (7) the experience and skill of the person who applied the technique on the occasion in question. ***Kelly v. State***, 792 S.W.2d 579 (Tex. App.-Fort Worth 1990).

Claimant failed to present an evidence-based medical opinion from a competent source to overcome the IRO's decision. Although the Claimant's pain management doctor, Dr. K, answered questions concerning the requested medications, he did not provide any documentation to support the long-term use of the prescribed medications for the Claimant's compensable injury. Dr. K's records, without sufficient reference to the *ODG* or other evidence-based medicine justifying departure from the *ODG,* do not meet the requisite evidentiary standard required to overcome the IRO. The preponderance of the evidence is not contrary to the IRO decision and the requested medications do not meet the criteria set out in the *ODG*.

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 _____, Claimant was the employee of (Employer).

   C. The IRO determined that the requested services were not reasonable and necessary health care services for the compensable injury of _____.

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. Neurontin 600mg, Percocet 10-325mg, and Valium 10mg is not health care reasonably required for the compensable injury of _____.

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 the Neurontin 600mg, Percocet 10-325mg, and Valium 10mg is not health care reasonably required for the compensable injury of _____.

DECISION

The Claimant is not entitled to Neurontin 600mg, Percocet 10-325mg, and Valium 10mg for the compensable injury of _____.

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 **TPCIGA FOR RELIANCE NATIONAL INDEMNITY COMPANY, AN IMPAIRED CARRIER** and the name and address of its registered agent for service of process is

TEXAS PROPERTY & CASUALTY INSURANCE GUARANTY ASSOCIATION
MARVIN KELLY, EXECUTIVE DIRECTOR
9120 BURNET ROAD
AUSTIN, TEXAS 78758

Signed this 25th day of May, 2010.

David Paul Weston
Hearing Officer