

MEDICAL CONTESTED CASE HEARING NO. 13001

**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 September 6, 2012, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that prescriptions for Lyrica on January 23, 2012, April 18, 2012, and May 11, 2012, and Soma on January 23, 2012, April 18, 2012, and May 11, 2012, are not reasonably required health care for the compensable injury of (Date of Injury)?

**PARTIES PRESENT**

Petitioner/Claimant appeared and was assisted by TM, ombudsman. Respondent/Carrier appeared and was represented by PB, attorney.

**BACKGROUND INFORMATION**

Claimant sustained a compensable back injury on (Date of Injury), and has undergone multiple surgeries as part of the health care to treat the compensable injury. Claimant's treating doctor, K F, DO prescribed Norco, Lyrica and Soma as part of the treatment regimen for Claimant's ongoing complaints of back pain. Carrier refused to authorize payment for the three drugs obtained pursuant to Dr. F's prescriptions in January, April and May of 2012. Claimant requested that Carrier's denial be reviewed by an Independent Review Organization (IRO) and the Texas Department of Insurance appointed Professional Associates as the IRO. In a report dated June 21, 2012, the IRO overturned Carrier's denial of the prescription for Norco (Hydrocodone) but upheld the denial of the prescriptions for Lyrica and Soma (Carisoprodol). Claimant asserts that the IRO's decision is contrary to the preponderance of the evidence-based medicine.

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. The statutory definition of "health care" includes prescription drugs. Texas Labor Code Section 401.011(19)(E). Health care reasonably required is 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. Texas Labor Code Section 401.011 (18a) defines "evidence based medicine" as 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 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."

The ODG provides the following guidance on the use of the prescription drugs at issue:

Carisoprodol (Soma®)

Not recommended. This medication is FDA-approved for symptomatic relief of discomfort associated with acute pain in musculoskeletal conditions as an adjunct to rest and physical therapy. (AHFS, 2008) This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of

benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a “Las Vegas Cocktail”); & (5) as a combination with codeine (referred to as “Soma Coma”). (Reeves, 1999) (Reeves, 2001) (Reeves, 2008) (Schears, 2004) (Owens, 2007) There was a 300% increase in numbers of emergency room episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) Intoxication appears to include subdued consciousness, decreased cognitive function, and abnormalities of the eyes, vestibular function, appearance, gait and motor function. Intoxication includes the effects of both carisoprodol and meprobamate, both of which act on different neurotransmitters. (Bramness, 2007) (Bramness, 2004) A withdrawal syndrome has been documented that consists of insomnia, vomiting, tremors, muscle twitching, anxiety, and ataxia when abrupt discontinuation of large doses occurs. This is similar to withdrawal from meprobamate. (Reeves, 2010) (Reeves, 2007) (Reeves, 2004) There is little research in terms of weaning of high dose carisoprodol and there is no standard treatment regimen for patients with known dependence. Most treatment includes treatment for symptomatic complaints of withdrawal. Another option is to switch to phenobarbital to prevent withdrawal with subsequent tapering. A maximum dose of phenobarbital is 500 mg/day and the taper is 30 mg/day with a slower taper in an outpatient setting. Tapering should be individualized for each patient. (Boothby, 2003) Hospital emergency department visits involving the misuse of carisoprodol have doubled over five years, study shows. (SAMHSA, 2011) The AGS updated Beers criteria for inappropriate medication use includes carisoprodol. (AGS, 2012) For more information and references, see Muscle relaxants. See also Weaning of medications.

### Pregabalin (Lyrica®)

Recommended in neuropathic pain conditions and fibromyalgia, but not for acute pain. Pregabalin (Lyrica®) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Pregabalin listing for more information and references. This Cochrane review concluded that pregabalin has proven efficacy in neuropathic pain conditions and fibromyalgia. A minority of patients will have substantial benefit with pregabalin, and more will have moderate benefit. Many will have no or trivial benefit, or will discontinue because of adverse events. Individualization of treatment is needed to maximise pain relief and minimise

adverse events. There is no evidence to support the use of pregabalin in acute pain scenarios. (Moore-Cochrane, 2009)

The general guidelines for anti-epilepsy drugs in the ODG are:

Anti-epilepsy drugs (AEDs) for pain

***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:*** (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  $\geq 34$ . 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)

#### **SPECIFIC ANTI-EPILEPSY DRUGS:**

**Pregabalin (Lyrica®, no generic available)** has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced the approval of pregabalin as the first approved treatment for fibromyalgia. (ICSI, 2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008) Dose adjustment is necessary in patients with renal insufficiency. The antiepileptic agents gabapentin and pregabalin have attained widespread usage in the treatment of painful diabetic peripheral neuropathy (DPN). This pooled analysis of 7 randomized controlled trials comparing different doses and frequencies of pregabalin for painful DPN concluded that pregabalin at increasing daily doses is associated with dose-related relief of pain and reduction in sleep interference in patients with painful DPN. (Freeman, 2008)

**Side-Effect Profile:** Pregabalin has been associated with many side effects including edema, CNS depression, weight gain, and blurred vision. Somnolence and dizziness have been reported to be the most common side effects related to tolerability. (Tassone, 2007) (Attal, 2006) Significant negative cognitive side

effects were documented in healthy volunteers at 600 mg per day in one study. (Salinsky, 2010) It has been suggested that this drug be avoided if the patient has a problem with weight gain. (Jensen, 2006)

***Dosing Information:***

***Diabetic neuropathy*** – Begin with 50 mg 3 times a day; may be increased in one week based on tolerability and effect to a maximum of 300 mg/day. (Doses up to 600 mg/day were evaluated with limited additional benefit and increase in side effects.)

***Postherpetic neuralgia*** - Begin with 50 mg three times a day for one week; may be increased to 100 mg three times a day after one week based on tolerability and effect. Dose may be increased as tolerated after two to four weeks up to 300 mg twice daily (maximum dose 600 mg/day). (ICSI, 2007)

***Trial period:*** There is no established trial period, but the onset of action is thought to be less than 1 week. (Attal, 2006)

***Weaning:*** Do not discontinue pregabalin abruptly and weaning should occur over a one-week period. Withdrawal effects have been reported after abrupt discontinuation.

In a letter dated January 18, 2012, Dr. F wrote that he has treated Claimant for many years and that Soma is beneficial in order to decrease muscle spasm related to multiple failed lumbar surgeries. Dr. F further wrote that the Soma has provided relief that other anti-spasmodic medications had not. In another letter, dated August 29, 2012, Dr. F wrote that he had attempted to change Claimant's anti-spasm medications on several different occasions, but Claimant obtained better relief with the Soma. The other drugs were not specified. Dr. F also wrote that Claimant continued to experience "chronic pain with radicular components" and the Lyrica and Norco provided symptom control.

The IRO physician reviewer stated that Lyrica is not recommended to treat chronic low back pain experienced by Claimant, in part, because there are no radicular signs or symptoms. Dr. F, on the other hand, specifically states that he prescribed Lyrica to treat Claimant's chronic pain with radicular components. Use of the Lyrica to treat radicular symptoms is consistent with the recommendations found in the ODG, as the physician reviewer noted. The physician reviewer's recommendation against continued use of Soma, however, is consistent with the recommendations in the ODG and Dr. F failed to address the concerns over the potential abuse of the Soma and Hydrocodone in tandem.

In determining the weight to be given to expert testimony, a trier of fact must first determine if the expert is qualified to offer it. The trier of fact must then determine whether the opinion is relevant to the issues at bar and whether it is based upon a solid foundation. An expert's bald assurance of validity is not enough. *See Black vs. 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 549 (Tex. 1995). Evidence is considered 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). A medical doctor is not automatically qualified as an expert on every medical question and an unsupported opinion has little, if any, weight. *Black v. Food Lion, Inc.*, 171 F.3rd 308 (5th Cir. 1999).

Dr. F has treated Claimant for a number of years and his failure to adequately document radicular symptoms does not mean that those symptoms do not exist. In light of the recommendations in the ODG, Dr. F' determination that Lyrica is an effective treatment for Claimant's chronic pain with a radicular component, and the uncertainty of the physician reviewer's conclusions in light of the lack of information about Claimant's radicular symptoms, the preponderance of the evidence based medicine is contrary to the IRO's determination that prescriptions for Lyrica are not reasonably required health care for the compensable injury of (Date of Injury).

The preponderance of the evidence based medicine is not contrary to the IRO's determination that Soma is not health care reasonably required for the compensable injury. The ODG, relying on scientific studies, finds that Soma may be effective for short term use for acute symptoms, but does not recommend its use for chronic pain. Dr. F' opinion that it is an effective drug to treat Claimant's chronic pain does not appear to take into account the negative ramifications of Soma's long term use. Claimant has failed to overcome the IRO determination that Soma is not reasonably required health care 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 the (Employer), Employer.
  - C. On (Date of Injury), Employer was a self-insured governmental subdivision of the State of Texas.
  - D. Claimant sustained a compensable injury on (Date of Injury).
  - E. The Texas Department of Insurance appointed Professional Associates as the Independent Review Organization (IRO) to review Carrier's denial of the prescriptions for Hydrocodone, Lyrica and Soma.
  - F. The IRO overturned the denial of the prescription for Hydrocodone, but upheld the denial of the prescriptions for Lyrica and Soma.
  - G. Petitioner timely appealed the IRO's determination upholding Carrier's denial of prescriptions for Lyrica and Soma.
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. Claimant's treating doctor, KF, DO, prescribed Lyrica for the treatment of chronic pain with a radicular component.
  4. Dr. F has documented that Lyrica is an effective treatment for Claimant's chronic lumbar pain with a radicular component.
  5. The prescription for Lyrica for the treatment of the compensable injury of (Date of Injury), is consistent with the ODG recommendations for the use of the drug.
  6. Prescription of Lyrica on January 23, 2012, April 18, 2012, and May 11, 2012, is reasonably required medical treatment for the compensable injury of (Date of Injury).
  7. Prescription of Soma on January 23, 2012, April 18, 2012, and May 11, 2012, is not reasonably required health care 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 contrary to the decision of IRO that prescription of Lyrica on January 23, 2012, April 18, 2012, and May 11, 2012 is not reasonably required medical care for the compensable injury of (Date of Injury).
4. The preponderance of the evidence is not contrary to the decision of IRO that prescription of Soma on January 23, 2012, April 18, 2012, and May 11, 2012 is not reasonably required medical care for the compensable injury of (Date of Injury).

### **DECISION**

Claimant is entitled to prescriptions for Lyrica on January 23, 2012, April 18, 2012, and May 11, 2012. Claimant is not entitled to prescriptions for Soma on January 23, 2012, April 18, 2012, and May 11, 2012.

### **ORDER**

Carrier is liable for the payment of prescriptions of Lyrica at issue in this hearing, but is not liable for the payment of prescriptions for Soma. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **(SELF-INSURED)** and the name and address of its registered agent for service of process is

**GL, CITY ATTORNEY  
(ADDRESS)  
(CITY), TX ZIP**

Signed this 10<sup>th</sup> day of September, 2012.

KENNETH A. HUCHTON  
Hearing Officer