MEDICAL CONTESTED CASE HEARING NO. 13082

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 April 4, 2013, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that prescription medications are not reasonably required health care for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was represented by FW, attorney. Respondent/Carrier appeared and was represented by PB, attorney.

BACKGROUND INFORMATION

Claimant sustained a compensable injury on (Date of Injury), as he was moving a grave marker. The weight of the grave marker has been estimated as between 300 and 450 pounds. As part of the treatment for his injury, Claimant has undergone conservative care and is in the current care of Dr. KF, DO who has administered trigger point injections and who also prescribes prescription pain pills, muscle relaxers and a third medication that, according to Claimant, is for headaches if he starts withdrawal from the pain medication. After a peer review, Carrier refused payment for the prescription medications. Carrier's refusal was appealed to an Independent Review Organization (IRO) in compliance with Commissioner's Rule 133.308. The IRO upheld Carrier's denial of the prescription medications. Claimant thereafter requested a contested case hearing to review the IRO's decision.

Texas Labor Code §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 includes prescription drugs (Texas Labor Code §401.011(19)(E)) and health care reasonably required is further defined 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. (Texas Labor Code §401.011(22a).) Health care under the Texas Workers' Compensation system must

be consistent with evidence based medicine if that evidence is available. Evidence based medicine is defined 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. (Texas Labor Code §401.011(18a).) 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 §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 §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(s), "A decision issued by an IRO is not considered an agency decision and neither the department nor the division is considered a party to an appeal. In a division 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."

Claimant testified that Dr. F prescribes Hydrocodone, Cyclobenzaprine, and Gabapentine in conjunction with trigger point injections. In an April 1, 2013, letter, Dr. F addressed the use of the drugs, stating:

> The [Claimant's compensable disc protrusion at C5-6 and non-compensable degeneration in the right facet joint] was painful and required the use of medication. I discussed with [Claimant] the standard treatment for his area to control pain on a semi acute basis (sic) of the uses of Vicodin. Since he is considered to be a candidate for surgery of the cervical spine, this will support indication for the use of the medication (sic) has been prescribed. Also, alternatively the anticonvulsant medications of Neurontin and muscle relaxants are also appropriate to use at this period of time.

With regard to the particular drugs discussed by Dr. F, the ODG provides, in part, the following direction:

Neurontin:

> ***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)
Specific pain states:
Acute pain: There is limited evidence to show that this medication is effective for acute pain, and for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005)
Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004)
CRPS: Recommended as a trial. (Serpell, 2002)
Fibromyalgia: Recommended as a trial. (Arnold, 2007)
Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007)
Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect.
Dosing Information:
Postherpetic neuralgia – Starting regimen of 300 mg once daily on Day 1, then increase to 300 mg twice daily on Day 2; then increase to 300 mg three times daily on Day 3. Dosage may be increased as needed up to a total daily dosage of

1800 mg in three divided doses. Doses above 1800 mg/day have not demonstrated an additional benefit in clinical studies. (Neurontin package insert)
Diabetic neuropathy (off-label indication) – Gabapentin dosages range from 900 mg to 3600 mg in three divided doses (Backonja, 2002) (Eisenberg, 2007). Gabapentin is 100% renally excreted.
Recommended Trial Period: One recommendation for an adequate trial with gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggest that if inadequate control of pain is found, a switch to another first-line drug is recommended. Combination therapy is only recommended if there is no change with first-line therapy, with the recommended change being at least 30%. (TCA, SNRI or AED). (Jensen, 2006) (Eisenberg, 2007)
Weaning and/or changing to another drug in this class: Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert) *When to switch to pregabalin:* If there is evidence of inadequate response, intolerance, hypersensitivity or contraindications. There have been no head-to-head comparison trails of the two drugs.

Muscle relaxants including Cyclobenzaprine:

Cyclobenzaprine (Flexeril®, Fexmid™, generic available, ER as Amrix®): Recommended for a short course of therapy. Immediate release (eg, Flexeril, generic) recommended over extended release (Amrix) due to recommended short course of therapy (also note substantial increase in cost for extended release without corresponding benefit for short course of therapy). Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a *number needed to treat* of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See *Cyclobenzaprine*. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate

reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004) A recent RCT found that time to relief was better with immediate release compared to extended release cyclobenzaprine. (Landy, 2011)

Side Effects: Include anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (*See, 2008*) (Toth, 2004)

Dosing: 5 mg three times a day. Can be increased to 10 mg three times a day. This medication is not recommended to be used for longer than 2-3 weeks. (*See, 2008*)

Discontinuation of Vicodin (included as an opiod):

6) When to Discontinue Opioids: See *Opioid hyperalgesia*. Also see *Weaning of Medications*. Prior to discontinuing, it should be determined that the patient has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. The patient should not be abandoned.

(a) If there is no overall improvement in function, unless there are extenuating circumstances
(b) Continuing pain with the evidence of intolerable adverse effects; lack of significant benefit (persistent pain and lack of improved function despite high doses of opiates- e.g. > 120 mg/day morphine equivalents)
(c) Decrease in functioning
(d) Resolution of pain
(e) If serious non-adherence is occurring
(f) The patient requests discontinuing
(g) Immediate discontinuation has been suggested for: evidence of illegal activity including diversion, prescription forgery, or stealing; the patient is involved in a motor vehicle accident and/or arrest related to opioids, illicit drugs and/or alcohol; intentional suicide attempt; aggressive or threatening behavior in the clinic. It is suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances.
(h) Many physicians will allow one “slip” from a medication contract without immediate termination of opioids/controlled substances, with the

consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat violations.

(i) If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion it has been suggested that a patient show evidence of a consult with a physician that is trained in addiction to assess the ongoing situation and recommend possible detoxification. (*Weaver, 2002*)

(j) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

(k) Routine long-term opioid therapy is not recommended, and ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support use. The research available does not support overall general effectiveness and indicates numerous adverse effects with long-term use. The latter includes the risk of ongoing psychological dependence with difficultly weaning. See Opioids for chronic pain.

7) When to Continue Opioids

(a) If the patient has returned to work

(b) If the patient has improved functioning and pain

(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)

Claimant testified that his prescription medications, specifically the Vicodin, was stolen from his vehicle when he allowed a friend's son to move his truck while at their house for a barbeque. He did not report the theft to the police. He did, however, call Dr. F's office to explain the situation. When he appeared at Dr. F's office four days later and was subjected to a urine drug screen, he did not have evidence of the drug in his urine. Claimant testified that Dr. F has continued to prescribe all three prescription drugs despite the loss of the Vicodin.

The ODG does not recommend the ongoing use of Cyclobenzaprine for more than three weeks. Claimant has been prescribed the drug for longer than the recommended period. The evidence failed to establish that Dr. F prescribes Neurontin for postherpetic neuralgia or neuropathic pain. Claimant's failure to report the alleged theft to the proper authorities or to obtain the return of the drug from the alleged thief whose identify was well known could be viewed as an indication of diversion. The discontinuation of Vicodin in this matter is consistent with the recommendation in the ODG that it be discontinued if there is an indication of diversion.

Dr. F's opinion that the prescription drugs are appropriate is at odds with the recommendations of the ODG. His conclusory statement that the drugs are appropriate, without explanation or

qualification, is not persuasive. Claimant has failed to prove that the preponderance of the evidence based medical evidence is contrary to the IRO decision upholding Carrier's denial of payment for prescription drugs.

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

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

3. On (Date of Injury), Employer provided workers' compensation insurance with the Insurance Company of the State of Pennsylvania, Carrier.

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

5. Carrier refused to continue paying for prescription drugs for the treatment of the compensable injury of (Date of Injury).

6. The Texas Department of Insurance appointed US Resolutions Inc. as the Independent Review Organization to review Carrier's denial payment for prescription medications.

7. On January 28, 2013, the IRO rendered its decision supporting Carrier's refusal to pay for prescription drugs as part of the medical care rendered for the compensable injury of (Date of Injury).

8. The determination of the IRO is consistent with the provisions of the ODG regarding the drugs prescribed by Dr. F, DO as part of the treatment for the compensable injury of (Date of Injury).

9. 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.

10. The drugs prescribed by Dr. F are 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 not contrary to the decision of IRO that prescription drugs are not reasonably required medical care for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to prescription drugs 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 **INSURANCE COMPANY OF THE STATE OF PENNSYLVANIA** and the name and address of its registered agent for service of process is

CORPORATION SERVICE COMPANY
211 EAST 7TH STREET, STE. 620
AUSTIN, TX 78701-3232

Signed this 9th day of April, 2013.

KENNETH A. HUCHTON
Hearing Officer