MEDICAL CONTESTED CASE HEARING NO. 10099
M6-10-21233-01

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 contested case hearing was held on January 7, 2010, 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 reimbursement for the drugs Oxycontin and Hydrocodone prescribed on July 3, 2009 for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by NO, ombudsman. Respondent/Carrier appeared and was represented by RJ, attorney.

BACKGROUND INFORMATION

Claimant injured his low back at work on _____. He has been treated conservatively with physical therapy, injections, and medications. Since 2003 Dr. RP, neurologist, has continuously prescribed Oxycontin and Hydrocodone for pain management. Based upon the October 14, 2008 report from Dr. AK, the carrier denied the continued use of these medications. The dispute was presented to an IRO doctor who determined, based on the Official Disability Guidelines (ODG) and medical judgment, there was a lack of documentation showing decreased pain and/or increased functionality and thus use of Oxycontin and Hydrocodone were no longer warranted. On July 3, 2009 Claimant spent $365.48 to refill prescriptions for Oxycontin and Hydrocodone and has brought this dispute to recover this amount.

Texas Labor Code Section 408.021 provides 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 that evidence 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, by 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 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 is 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 places the two medications under “opioids” and defines them as:

> *"Hydrocodone/Acetaminophen (Anexsia®, Co-Gesic®, Hycet™; Lorcet®, Lortab®; Margesic-H®, Maxidone™; Norco®, Stagesic®, Vicodin®, Xodol®, Zydone®; generics available):* Indicated for moderate to moderately severe pain. Note: there are no FDA-approved hydrocodone products for pain unless formulated as a combination. Side Effects: See opioid adverse effects. Analgesic dose: The usual dose of 5/500mg is 1 or 2 tablets PO every four to six hours as needed for pain (Max 8 tablets/day). For higher doses of hydrocodone (>5mg/tab) and acetaminophen (>500mg/tab) the recommended dose is usually 1 tablet every four to six hours as needed for pain. Hydrocodone has a recommended maximum dose of 60mg/24 hours. The dose is limited by the dosage of acetaminophen, which should not exceed 4g/24 hours.
>
> *Oxycodone immediate release (OxyIR® capsule; Roxicodne® tablets; generic available), Oxycodone controlled release (OxyContin®):* [Boxed Warning]: Oxycontin® Tablets are a controlled release formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. Oyxcontin tablets are NOT intended for use as a prn analgesic. Side Effects: See opioid adverse effects. Analgesic dose: (Immediate release tablets) 5mg every 6 hours as needed. Controlled release: In opioid naive patients the starting dose is 10mg every 12 hours. Doses should be tailored for each individual patient, factoring in medical condition, the patient’s prior opioid exposure, and other analgesics the patient may be taking. See full prescribing information to calculate conversions from other opioids. Note: See manufacturer’s special instructions for prescribing doses of over 80mg and 160mg. Dietary caution: patients taking 160mg tablets should be advised to avoid high fat meals due to an increase in peak plasma concentration. (Product information, Purdue Pharma)"

Both of these medications refer the reader to "Opioids" in the ODG. Below are applicable sections from the ODG for Opioids:

> “CRITERIA FOR USE OF OPIOIDS:
>
> *Recommendations for general conditions:*
> - *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)

Long-term Users of Opioids (6-months or more)

1) Re-assess

(a) Has the diagnosis changed?

(b) What other medications is the patient taking? Are they effective, producing side effects?

(c) What treatments have been attempted since the use of opioids? Have they been effective? For how long?

(d) Document pain and functional improvement and compare to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument.

(e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation.

(f) Does the patient appear to need a psychological consultation? Issues to examine would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships.

(g) Is there indication for a screening instrument for abuse/addiction? See Substance Abuse Screening.

4) On-Going Management. Actions Should Include:
(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.
(b) The lowest possible dose should be prescribed to improve pain and function.
(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. *The 4 A's for Ongoing Monitoring*: Four domains have been proposed as most relevant for ongoing

monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)

(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.

(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (Webster, 2008)

(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).

(g) Continuing review of overall situation with regard to nonopioid means of pain control.

(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007)

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.

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)"

In this case, the IRO doctor was supplied with the pain management records. After the review, the IRO doctor stated it was not possible to determine from Dr. P's records any change in Claimant's condition for better or worse which justified the continued use of opioids. The IRO doctor went on to state that Claimant should be weaned from the medications as recommended in the ODG.

There was no documentation in the medical records of a measurement of baseline function or objective evidence noted of functional improvement with use of Oxycontin and Hydrocodone. Claimant attempted to supply this evidence by his oral testimony that he was able to get around much better while on the medication and attend to some tasks around his home which he was unable to do without the medication. Even though a medical letter from Dr. EF explained that Claimant should avoid usage of nonsteroidal anti-inflammatory medications due to another medical condition, the requirements of the ODG relating to treatment options and functional improvement documentation with opioids usage were not met. Claimant did not meet his burden of proof to show that the preponderance of evidence based medicine was contrary to the IRO decision.

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. On _____, Claimant sustained a compensable injury.

D. The Independent Review Organization determined Claimant was not entitled to reimbursement for the drugs Oxycontin and Hydrocodone prescribed on July 3, 2009.

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. Medical records fail to document significant pain relief or improvement in function as a result of use of Oxycontin and Hydrocodone medication as required by the ODG.

4. The use of Oxycontin and Hydrocodone, and reimbursement for the drugs, as prescribed on July 3, 2009, are 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 reimbursement for the drugs Oxycontin and Hydrocodone prescribed on July 3, 2009 are not health care reasonably required for the compensable injury of _____.

DECISION

Claimant is not entitled to reimbursement for the drugs Oxycontin and Hydrocodone prescribed on July 3, 2009 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 **LM INSURANCE CORPORATION** and the name and address of its registered agent for service of process is

CORPORATION SERVICES COMPANY
701 BRAZOS STREET, SUITE 1050
AUSTIN, TX 78701.

Signed this 7th day of January, 2010.

Judy L. Ney
Hearing Officer