MEDICAL CONTESTED CASE HEARING NO. 09124
M6-09-17342-01

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 March 26, 2009, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the Claimant is entitled to continued Cymbalta and is not entitled to continued Hydrocodone and Avinza?

During opening arguments, it was agreed the IRO's determination that Cymbalta should be continued was not being disputed and could be removed from the issue to be adjudicated. The issue then became the following:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the Claimant is not entitled to continued Hydrocodone and Avinza?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by EJ, ombudsman. Respondent/Carrier appeared and was represented by JC, attorney.

BACKGROUND INFORMATION

Claimant is a registered nurse who slipped and fell backward onto her back. Since that time she has developed chronic pain that originates in her back and travels to her left foot. Her treatment has been extensive. Along with other conservative care, she has undergone 20 sessions of a chronic pain management program, had a spinal cord stimulator implanted and has most recently been placed on a narcotics regimen that consists of Cymbalta, Avinza and Hydrocodone for breakthrough pain. The Carrier denied and disputed the continued use of these medications because it determined there was a lack of documentation showing decreased pain and/or increased functionality. Eventually the dispute was presented to an IRO doctor who determined, based on the Official Disability Guidelines and medical records provided, Claimant's continued use of Cymbalta was medically necessary, but her continued use of Avinza and Hydrocodone were no longer warranted. The Carrier did not dispute the decision supporting the continued use of Cymbalta. The Claimant is disputing the denial of the Avinza and Hydrocodone.

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. Section 401.011(22-a) defines health care reasonably required 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: (A) evidence based medicine; or (B) if that evidence is not available, generally accepted standards of medical practice recognized in the

medical community." "Evidence based medicine" is further defined, by Section 401.011(18-a) 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.

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, 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 Official Disability Guidelines.

Pursuant to the Official Disability Guidelines for Avinza:

> Avinza capsules are a brand of modified-release morphine sulfate indicated for once daily administration for the relief of moderate to severe acute or breakthrough pain requiring continuous, around-the-clock opioid therapy for an extended period of time, supplied by King Pharmaceuticals, Inc. See Opioids for recommendations and references.

Pursuant to the Official Disability Guidelines for Hydrocodone:

> Hydrocodone is a semi-synthetic opioid which is considered the most potent oral opioid that does not require special documentation for prescribing in some states (not including California). See Opioids

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

> *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, and long-term efficacy is unclear (>16 weeks), but also appears limited. 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)
> - *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 (less than or equal to 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.

The applicable sections of the Official Disability Guidelines for continued use of opioids is the following:

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 a great deal of medical records. The doctor provided a comprehensive summary of Claimant's clinical history. After the review, the IRO doctor stated there is no finding of any substantial pathology which justified opioids for Claimant. The doctor stated all previous testing has been relatively unremarkable and the EMG studies were of questionable utility. He stated there has not been a consensus as to the exact nature of the diagnosis. He states the ongoing use of high doses of opioids does not appear to be reasonably necessary or supported by objective testing. He stated Claimant should be weaned from the medications as recommended and based on the Official Disability Guidelines. (Claimant is currently being weaned from the Avinza and Hydrocodone per an agreement with the adjuster and her doctor based on the IRO opinion.)

The problem with the IRO opinion is none of the reasons the doctor gives for discontinuing Avinza and Hydrocodone for chronic pain are listed in the Official Disability Guidelines. Claimant's doctor addressed the IRO report in Claimant's Exhibit No. 6. He stated the IRO decision was incorrect in that the reviewer based his decision on evaluating the diagnostic studies and not the patient herself. The Official Disability Guidelines addresses this when it states:

> 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)

None of these measures includes a specific diagnosis, a finding of substantial pathology or objective testing results.

Claimant testified her pain decreased with the use of these medications and her functionality increased by using the current levels of Avinza and Hydrocodone. She and the doctor followed the guidelines outlined in the Criteria for Use of Opioids noted above. They did a trial of opioids as the first step for treatment. They then titrated to the current levels of Avinza and the occasional use of Hydrocodone for breakthrough pain. They are now at the functional, lowest level, maintenance phase. Without these medications, Claimant testified she would return to being unable to function, including being unable to do simple chores and go to church. Claimant testified she even has a job lined up as long as she is able to function and she cannot do this without her medications. Her doctor states Claimant is continuing to show improved pain control and a higher level of functioning, as required by the Official Disability Guidelines.

The pain management doctor provided evidence based medicine in accordance with the Official Disability Guidelines by documenting Claimant's increased level of function and improved quality of life. Given that, a fair reading of the medical records, the pain management doctor's report, and other credible medical evidence shows the Official Disability Guidelines recommendations with respect to the continued use of Avinza and Hydrocodone were followed. The decision of the IRO is contrary to the preponderance of evidence-based medical evidence. Petitioner met her burden of proof.

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 should have continued Cymbalta and should not have continued Hydrocodone or Avinza.

   E. The Independent Review Organization's determination Cymbalta was warranted is not disputed by the Carrier.

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 3.

3. Continued Hydrocodone and Avinza are 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 contrary to the decision of the IRO that continued Hydrocodone and Avinza are not health care reasonably required for the compensable injury of _____.

DECISION

Claimant is entitled to continued Hydrocodone and Avinza for the compensable injury of _____.

ORDER

Carrier is 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 **AMERICAN CASUALTY COMPANY OF READING, PENNSYLVANIA** and the name and address of its registered agent for service of process is

CT CORPORATION SYSTEM
350 N. ST. PAUL STREET
DALLAS, TX 75201.

Signed this 01st day of April, 2009.

KEN WROBEL
Hearing Officer