

MEDICAL CONTESTED CASE HEARING NO. 12107  
M6-12-38918-01

**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 1, 2012 to decide the following disputed issues:

Is the preponderance of the evidence contrary to the decision of the Independent Review Organization that Claimant is not entitled to sixty tablets of Vicodin 5/500 mg twice per day as needed for pain for the compensable injury of (Date of Injury)?

**PARTIES PRESENT**

Claimant appeared, and was assisted by Ombudsman BO; Carrier appeared, and was represented by Attorney RR.

**BACKGROUND INFORMATION**

Claimant sustained a compensable low-back injury, which has been treated with medication, epidural steroid injections, and surgery. Despite such treatment, she continues to experience severe pain, and uses her prescribed Vicodin to ease her pain to a degree.

Dr. K, M.D., a physical medicine and rehabilitation specialist retained by Carrier, testified that Claimant's continued use of Vicodin did not meet the Official Disability Guidelines, as Claimant had not returned to work, and had not demonstrated improved pain or functioning. He further noted that Claimant's documented anxiety constituted a "red flag" for opioid use.

**DISCUSSION**

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(22-a) 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(18-a) 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. 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 [a party] 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."

With regard to opioid use, the ODG states as follows:

This topic is covered under multiple headings. See more specific entries, as follows:  
**Opioids, criteria for use;** Opioids for chronic pain; Opioids for neuropathic pain; Opioids for osteoarthritis; Opioids, cancer pain vs. nonmalignant pain; Opioids, dealing with misuse & addiction; Opioids, differentiation: dependence & addiction; Opioids, dosing; Opioids, indicators for addiction; Opioids, long-term assessment; Opioids, pain treatment agreement; Opioids, psychological intervention; Opioids, specific drug list; Opioids, screening for risk of addiction (tests); Opioids, state medical boards guidelines; Opioids, steps to avoid misuse/addiction; Detoxification; Substance abuse (tolerance, dependence, addiction); Urine Drug Testing (UDT) in patient-centered clinical situations; Weaning of medications; Implantable drug-delivery systems (IDDSs); Methadone; Rapid detox; Testosterone replacement for hypogonadism (related to opioids); Opioid hyperalgesia & Opioids, specific drug list. Opioid drugs are also referred to as opiate analgesics, narcotic analgesics, or schedule C (II -IV) controlled substances. Opioid analgesics are a class of drugs (e.g., morphine, codeine, and methadone) that have a primary indication to relieve symptoms related to pain. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage both acute and chronic pain. These medications are generally classified according to potency and duration of dosage duration.

### ***Overall Classification:***

*Pure-agonists:* include natural and synthetic opioids such as morphine sulfate (MS Contin®), hydromorphone (Dilaudid®), oxymorphone (Numorphan®), levorphanol (Levo-Dromoran®), codeine (Tylenol w/Codeine 3®), hydrocodone (Vicodin®), oxycodone (OxyContin®), methadone (Dolophine HCl®), and fentanyl (Duragesic®). This group of opioids does not have a ceiling effect for their analgesic efficacy nor do they antagonize (reverse) the effects of other pure opioids. (Baumann, 2002) Morphine is the most widely used type of opioid analgesic for the treatment of moderate to severe pain due to its availability, the range of doses offered, and its low cost.

*Partial agonists-antagonists:* agents that stimulate the analgesic portion of opioid receptors while blocking or having little or no effect on toxicity. This group of opiates includes buprenorphine (Suboxone®). Partial agonists-antagonists have lower abuse potential than pure-agonists, however the side effects of this class of analgesics include hallucinations and dysphoria. *Opioid antagonists* such as naloxone are included in this class. They are most often used to reverse the effects of agonists and agonist-antagonist derived opioids. (Baumann, 2002)

*Mixed agonists-antagonists:* another type of opiate analgesics that may be used to treat pain. They include such drugs as butorphanol (Stadol®), dezocine (Dalgan®), nalbuphine (Nubain®) and pentazocine (Talwin®). (Baumann, 2002) Mixed agonists-antagonists have limited use among chronic pain patients because of their ceiling effect for analgesia that results in the analgesic effect not increasing with dose escalation.

*Central acting analgesics:* an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g., Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram®) are reported to be effective in managing neuropathic pain. (Kumar, 2003) Side effects are similar to traditional opioids.

### ***Opioid Classifications: Short-acting/Long-acting opioids:***

*Short-acting opioids:* also known as “normal-release” or “immediate-release” opioids are seen as an effective method in controlling both acute and chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short-acting agents due to their adverse effects. The duration of action is generally 3-4 hours. Short-acting opioids include Morphine (Roxanol®), Oxycodone (OxyIR®, Oxyfast®), Endocodone®, Oxycodone with acetaminophen, (Roxilox®, Roxicet®, Percocet®, Tylox®, Endocet®), Hydrocodone with

acetaminophen, (Vicodin®, Lorcet®, Lortab®, Zydone®, Hydrocet®, Norco®), Hydromorphone (Dilaudid®, Hydrostat®). (Baumann, 2002)

*Long-acting opioids:* also known as “controlled-release”, “extended-release”, “sustained-release” or “long-acting” opioids, are a highly potent form of opiate analgesic. The proposed advantage of long-acting opioids is that they stabilize medication levels, and provide around-the-clock analgesia. Long-acting opioids include: Morphine (MSContin®, Oramorph SR®, Kadian®, Avinza®), Oxycodone (Oxycontin®), Fentanyl (Duragesic Patch®), Hydromorphone (Palladone®). Note: On 01/26/10 Purdue Pharma suspended Palladone® from the US market due to adverse effects with alcohol. (FDA, 2010) The odds of being hypogonadal

## **CRITERIA FOR USE OF OPIOIDS**

### **Therapeutic Trial of Opioids**

- 1) **Establish a Treatment Plan.** The use of opioids should be part of a treatment plan that is tailored to the patient. Questions to ask prior to starting therapy:
  - (a) Are there reasonable alternatives to treatment, and have these been tried?
  - (b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications?
  - (c) Has the patient received a screen for the risk of addiction? Is there likelihood of abuse or an adverse outcome? Specific questions about current use of alcohol, illegal drugs, other prescription drugs, and over-the counter drugs should be asked. Obtaining a history of personal and/or family substance abuse issues is important. See Substance abuse (tolerance, dependence, addiction). See Opioids, screening for risk of addiction. (Webster, 2008) (Ballyantyne, 2007)
  - (d) Ask about Red Flags indicating that opioids may not be helpful in the chronic phase:
    - (1) Little or no relief with opioid therapy in the acute and subacute phases.
    - (2) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression, or a previous history of substance abuse). Patients may misuse opioids prescribed for pain to obtain relief from depressed feelings, anxiety, insomnia, or discomforting memories. There are better treatments for this

type of pathology. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008)

- (e) 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.

## **2) Steps to Take Before a Therapeutic Trial of Opioids:**

- (a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain.
- (b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics.
- (c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals.
- (d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale. See Function Measures.
- (e) Pain related assessment should include history of pain treatment and effect of pain and function.
- (f) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function.
- (g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007)
- (h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.
- (i) A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver

attitudes about medicines may influence the patient's use of medications for relief from pain. See Guidelines for Pain Treatment Agreement. This should include the consequences of non-adherence.

- (j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs.

### **3) Initiating Therapy**

- (a) Intermittent pain: Start with a short-acting opioid trying one medication at a time.
- (b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of “rescue” opioids. The need for extra opioid can be a guide to determine the sustained release dose required.
- (c) Only change 1 drug at a time.
- (d) Prophylactic treatment of constipation should be initiated.
- (e) If partial analgesia is not obtained, opioids should be discontinued.

### **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 diary 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)

**5) Recommended Frequency of Visits While in the Trial Phase (first 6 months):**

- (a) Every 2 weeks for the first 2 to 4 months
- (b) Then at approximate 1 ½ to 2-month intervals

*Note:* According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. (California, 1994)

**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 difficulty 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)

A review of the IRO's report indicates that the requested Vicodin was denied on the basis that Claimant had not shown that she met the above requirements for continued use. This assessment of the situation is not altered by the medical reports in evidence, which state simply that Claimant's use of opioid medication allows her to function, without offering any specific information regarding Claimant's allegedly improved function or quality of life. Other medical records in evidence reveal that Claimant's use of prescribed opioids improves her pain by only one or two points on the visual analog scale. In short, Claimant has not shown that she has returned to work, and has provided no specific medical evidence that her medication use has, in fact, improved her functioning and pain; Claimant therefore has not shown that she meets the ODG criteria for continued opioid use, and a decision in favor of Carrier will therefore be entered as to the sole issue presented for resolution herein.

Even though all the evidence presented may not have been discussed in detail, it was considered; the Findings of Fact and Conclusions of Law are based on all of the evidence presented.

### **FINDINGS OF FACT**

1. On (Date of Injury), Claimant was employed by the (Employer), Employer.
2. On (Date of Injury), Employer subscribed to a policy of workers' compensation insurance issued by the Indemnity Insurance Company of North America, Carrier.
3. On (Date of Injury), Claimant's residence was located within seventy-five miles of the (City) office of the Texas Department of Insurance, Division of Workers' Compensation.
4. 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.
5. On (Date of Injury), Claimant sustained damage or harm to the physical structure of her body while she was within the course and scope of her employment with Employer.
6. The injury referenced in the previous Finding of Fact arose out of Claimant's employment with Employer.

7. Sixty tablets of Vicodin 5/500 mg. twice per day as needed for pain is not health care reasonably required for Claimant's 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-based medicine is not contrary to the decision of the Independent Review Organization that sixty tablets of Vicodin 5/500 mg. twice per day as needed for pain is not health care reasonably required for Claimant's compensable injury of (Date of Injury).

### **DECISION**

Claimant is not entitled to sixty tablets of Vicodin 5/500 mg twice a day for pain for her 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 the **INDEMNITY INSURANCE COMPANY OF NORTH AMERICA**. The name and address of Carrier's registered agent for service of process is:

**CT CORPORATION SYSTEM  
350 NORTH ST PAUL STREET  
DALLAS, TEXAS 75201**

Signed this 7<sup>th</sup> day of May, 2012.

Ellen Vannah  
Hearing Officer