MEDICAL CONTESTED CASE HEARING NO. 12131
M6-12-39165-01

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 August 13, 2012, 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 180 tablets of oxycodone 30mg/tab and/or OxyContin 80 mg q6hrs 120 for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by JM, ombudsman.
Respondent/Carrier appeared and was represented by GP, attorney.

BACKGROUND INFORMATION

The Claimant sustained a compensable injury on (Date of Injury), while lifting a 60 lb block over his head and his foot slipped. The Claimant stopped the block from falling and injured his spine and spinal cord. He had a failed fusion surgery and two additional surgeries in order to implant a morphine pump, which he currently has. The Claimant testified that he cannot function without the additional pain medications at issue, and has unsuccessfully attempted to be weaned several times. The IRO for both medications was a doctor who is board certified in anesthesiology. The IRO concluded that neither medication in the requested amounts is medically necessary because they are inordinately high doses and the Claimant needs to be weaned. The IRO further noted that the Claimant is at a very high risk for an adverse event and that his opiate use exceeds the ODG recommendations for the management of chronic pain.

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 (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. Evidence based medicine is further defined in Texas Labor Code 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 in making decisions for 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."

Opioid dosing:

Recommend that dosing not exceed 120 mg oral morphine equivalents per day. Opioids may be recommended as a 2nd or 3rd line treatment at doses ≤ 120 mg daily oral morphine equivalent dose (MED). See Opioids for chronic pain. Risk benefit of use should be evaluated, including that of substance abuse and death. An accurate diagnosis should be established and it is strongly recommended that a psychological evaluation occur before starting this class of drugs. Escalation of doses greater that 120 mg (MED) should be done with caution, and generally under the care of pain specialists, and in certain cases, addiction specialists, with the understanding that many patients who progress to chronic opioid therapy have underlying psychiatric disease and substance abuse issues. Different formulations of opioids can be compared in terms of doses by converting to morphine equivalents. The table below lists standard conversion factors although there are drawbacks to equivalency tables because they do not consider a recommended dose reduction for opioid cross-tolerance. The Washington State Agency Medical Director’s Group guidelines includes a convenient opioid conversion table. (AMDG, 2007)

Methadone: Methadone conversion requires careful consideration because of its long half-life and unusual pharmacokinetic profile compared with most other opioids. In addition, converting

methadone to morphine is not bidirectional. When switching from an established dose of methadone to another opioid, we must consider that measurable methadone serum levels will be around for days, so both drugs are now readily available, increasing the overall risk for opioid toxicity. (Fudin, 2008)

Opioid Dosing Calculator

Morphine Equivalent Dose (MED) factor:

Codeine - 0.15

Fentanyl transdermal (in mcg/hr) - 2.4

Hydrocodone - 1

Hydromorphone - 4

Methadone, 41 to 60mg per day - 10

Methadone, >60mg per day - 12

Morphine - 1

Oxycodone - 1.5

Oxymorphone – 3

Opioids for chronic pain:

Not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Recommended as a 2nd or 3rd line treatment option at doses ≤ 120 mg daily oral morphine equivalent dose (MED) as indicated below. Risk-benefit of use should be carefully weighed for substance abuse and overdose risks, including risk of death, and this information should be provided to the patient as part of informed decision-making. Extreme caution is required for any opioid use in patients with the following: (1) Individuals with a high risk for misuse or diversion; (2) Individuals with evidence of substance abuse issues; (3) Individuals with a family history of substance abuse; (4) Individuals with underlying psychiatric disease. An accurate diagnosis should be established. At the minimum, screening for opioid risk and psychological distress inventories should occur before starting this class of drugs and a psychological evaluation is strongly recommended. Escalation of doses beyond 120 mg MED should be done with caution, and generally under the care of pain specialists. In certain cases, addiction specialists may need to evaluate patients, with the understanding that many patients who progress to chronic opioid therapy have underlying psychiatric disease and substance abuse issues. While long-term opioid therapy may benefit

some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective in achieving the original goals of complete pain relief and functional restoration. For patients now on high opioid doses who are not benefiting from them, if taken off the medications many would experience severe withdrawal or have to take addiction treatment drugs for years. See Weaning of medications. To prevent new patients from getting caught in this cycle, ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases.

Use for specific disease states

- *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, where opioids are not recommended as a first-line therapy.

- *Chronic back pain:* Opioids appear to be efficacious but should be limited for short-term pain relief in patients with acute low back pain. 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) (White, 2011) (Franklin, 2009) Failure of activity level to respond to a time-limited course of opioids has led to the suggestion of reassessment 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 indicates 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 did not necessarily improve function. (Deshpande, 2007) See also the Low Back Chapter for recommendations in acute pain, where opioids are not recommended except for short use for severe cases, not to exceed 2 weeks.

- *Headaches:* Not recommended, in particular, due to the risk of medication overuse headache. (Lake, 2008) (Olesen, 2006) See Medication overuse headache.

- *Osteoarthritis:* Not recommended as a first-line therapy. Recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or NSAIDs when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. There is a lack of evidence to allow for a treatment recommendation for long-term use. If used on a long-term basis, the criteria for use of opioids should be followed. See Opioids for osteoarthritis for citations. The American College of Rheumatology guidelines do not recommend opioids for osteoarthritis, except in patients who should have total joint arthroplasty but cannot. (Hochberg, 2012)

- ***Nociceptive pain:*** Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury, with the most common example being pain secondary to cancer).

- *Mechanical and compressive etiologies*: rarely beneficial.

Evidence for use*:* A major concern about the use of opioids for chronic pain is that most randomized-controlled trials are limited to a short-term period (1 to 6 months), with high rates of dropout due to adverse effects and/or lack of efficacy (as high as 60%). Studies usually exclude patients with mental health disease or substance abuse, limiting generalizability. Methodological issues result in limitations, with problems of studies including insufficiently comprehensive outcome assessment, and incomplete inclusion of adverse effects. Results suggest modest pain relief compared to placebo (approximately 30%), but there are no long-term studies to determine if pain relief is maintained. Overall, the safety of long-term use has not been adequately studied, and some nonrandomized prospective studies suggest opioid treatment may actually retard functional recovery. 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. (Eriksen, 2006) (Ballantyne, 2006) (Furlan, 2006) (Ballantyne, 2008) (Franklin, 2008) (Chou, 2009) (Chapman, 2010) (Papaleontiou, 2010) (Furlan, 2010) (Von Korff, 2011) (Manchikanti, 2011)

Upper limits of range of dose*:* The Washington State Department of Labor and Industries Guidelines suggest that the "upper limit of range" for opioids prior to evaluation with a pain specialist for the need for possible continuation of treatment, escalation of dose, or possible weaning, is 120 mg of oral morphine equivalents a day (MED). These values are based on factors such as evidence of increased risk of alcohol- or drug-related encounters (alcohol or drug intoxication, alcohol or drug withdrawal, or alcohol or drug overdose) at higher doses. Risk increases with a history of previous or ongoing substance abuse and concomitant use of opioids with sedative hypnotics and/or benzodiazepines. Progression to long-term use also increases with prescribing of higher doses of opioids. Other cohort studies have indicated lower rates of return to work, higher rate of healthcare utilization, and higher rates of going on to receive Social Security Disability Income with higher doses of opioids. With the introduction of a definition of high dose of opioids as ≥ 120 mg by the Washington State workers' compensation system, there was a 27% decrease in average morphine equivalents a day dispensed, a 35% decrease in the number of patients receiving > 120 mg/day of morphine equivalents (both compared to before 2007), and a 50% decrease in number of unintentional opioid deaths (2009-2010). (Ballantyne, 2006) (AMDG, 2007) (Kidner, 2009) (Kidner, 2010) (Braden, 2009) (Braden, 2010) (Dunn, 2010) (Bohnert, 2011) (Martin, 2011) (Franklin, 2012) See Opioids, dosing (morphine equivalent dose).

Patients most likely to receive high-dose opioids: Cohort studies indicate that small proportions of patients are most likely to receive the majority of opioids (in one study 5% of patients received 70% of opioids dispensed). Patients most likely to receive high-dose opioids in cohort studies are those who have multiple pain complaints, and have mental health and substance use disorders. These are generally patients who are excluded from randomized trials of opioids, which limit the generalizability of current studies. They are also more likely to be receiving concomitant benzodiazepines. Studies show these patients are more likely to have higher rates of medical diagnoses and higher Charlson comorbidity scores. (Sullivan, 2005) (Braden, 2009) (Edlund 2010) (Morasco, 2010) (Kidner, 2010) (Sullivan, 2012)

Risk factors for progressing to long-term opioid use: It is currently suggested that of the patients that proceed to long-term opioid use (90 days or more), two-thirds continue opioids for years later, creating life-long therapy. Current research involves evaluating what subsets of patients are likely to proceed to long-term use, particularly as (1) the vast majority of patients in randomized-controlled studies abandon opioids after short-term use due to adverse effects and/or lack of efficacy and (2) a small proportion of patients receive the majority of opioids dispensed. Subclasses of individuals who continue with long-term use have been identified as patients who use high daily doses (>120 mg morphine equivalent/day) and/or have a history of opioid misuse. The likelihood of receiving long-term opioids increases with number of pain sites, increased baseline pain, decreased baseline function, number of medical diagnoses, nicotine dependence, psychiatric diagnoses, lower self-reported mental health, fear avoidance beliefs, and lower certainty of return to work in the next six months. The most likely mental health diagnoses are anxiety disorder and post-traumatic stress disorder. It is suggested that long-term opioids are often unknowingly being used to treat the sequelae of both physical and psychological trauma. This is based on theories of endogenous opioid system disruption. (Sullivan, 2005) (Webster, 2007) (Dersh, 2007) (Dersh, 2008) (Weisner, 2009) (Braden, 2009) (Franklin, 2009) (Edlund 2010) (Morasco, 2010) (Martin, 2011) (Sullivan, 2012)

Adverse effects: These include serious fractures, sleep apnea, hyperalgesia, immunosuppression, chronic constipation, bowel obstruction, myocardial infarction, and tooth decay due to xerostomia. Neuroendocrine problems include hypogonadism, erectile dysfunction, infertility, decreased libido, osteoporosis, and depression.

Risk of overdose: Since 2003, more overdose deaths have involved prescription opioid analgesics than heroin or cocaine combined. The CDC estimates that in 2008 there were almost 100 drug overdose deaths a day (in numbers nearing that of deaths from motor vehicle accidents). Opioid pain relievers accounted for 73.8% of deaths, with prescription drugs accounting for the largest increase in deaths. (MMWR, 2011) The risk of overdose increases when opioids are used with other drugs (such as benzodiazepines, cocaine, and/or heroin) or alcohol. Other risk factors include a history of substance abuse and/or of mental health disorder. The CDC states that the two main populations at risk for overdose are the approximate 9 million

individuals who report long-term use of opioids, and the 5 million individuals who report non-medical use of this class of drugs. The CDC also reports increased risk for individuals on high doses of daily opioids (defined as > 100 mg of oral morphine equivalents a day) who seek care from multiple providers. Individuals with these characteristics were found to represent 40% of overdose deaths. Another concern is that this is a group of individuals who are likely to divert drugs. Statewide data has found that 25% to 66% of those who die of pharmaceutical overdose were taking drugs prescribed to someone else. (Mirakbari, 2003) (CDC, 2012) (CDC, 2011) (Webster, 2011). (Gomes, 2011) (Dunn, 2010) (Bohnert, 2011) (Bohnert 2012)

Concomitant use with other medications: Benzodiazepines and other sedative drugs*:* Benzodiazepines are commonly implicated in opioid overdose deaths and they lower the lethal opioid dose. Consideration of tapering the use of sedative hypnotics and benzodiazepines before starting opioid use if possible is strongly recommended. (Mirakbari, 2003) (Kahan, 2011) (Gomes, 2011) (Toblin 2010)

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)

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 for chronic pain as a first step in treatment for appropriate conditions that have not responded to other interventions after careful screening and patient informed consent. 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.

- 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) (VA/DOD, 2010) 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.

In support of his position, the Claimant offered a letter from Dr. MM who stated that the Claimant's medications should be continued because he has been on them for many years without adverse effect. *Additionally*, he stated that his function is improved and that it is the lowest amount possible for his treatment. He further stated that it would create an unreasonable risk of medical emergency if the Claimant is taken off the medications. However, other medical records from Dr. M facility show that he agrees that the Claimant needs to be weaned. The Claimant failed to present evidence-based medicine that overcomes the decision of the IRO that the medications at the levels requested are not medically necessary.

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 (Employer), Employer and sustained a compensable injury.

   C. On (Date of Injury), the Employer provided worker's compensation insurance through the Insurance Company of the State of Pennsylvania.

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. 180 tablets of oxycodone 30mg/tab and/or OxyContin 80 mg q6hrs 120 is not health care reasonably required for the compensable injury of (Date of Injury).

4. On January 31, 2012, an IRO held that 180 tablets of oxycodone 30mg/tab was not medically necessary for the compensable injury of (Date of Injury).

5. On February 7, 2012, an amended IRO decision held that OxyContin 80 mg q6hrs 120 was not medically necessary 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 decisions of the IRO that 180 tablets of oxycodone 30mg/tab or OxyContin 80 mg q6hrs 120 is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to 180 tablets of oxycodone 30mg/tab and/or OxyContin 80 mg q6hrs 120 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, SUITE 620
(CITY), TEXAS 78701-3218

Signed this 17th day of August, 2012.

Cristina Beciro
Hearing Officer