MEDICAL CONTESTED CASE HEARING NO. 18032

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. For the reasons discussed herein, the Administrative Law Judge determines that NDC – 552890651 NORCO 10/325 MG TID #90 is not health care reasonably required for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

A contested case hearing was held on December 4, 2018 to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the IRO that Claimant is not entitled to NDC – 552890651 NORCO 10/325 MG TID #90 for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Claimant appeared and was assisted by MH, ombudsman. Carrier appeared and was represented by GS, attorney.

EVIDENCE PRESENTED

The following witnesses testified:

For the Claimant: MF.

For Carrier: None.

The following exhibits were admitted into evidence:

Administrative Law Judge's Exhibits ALJ-1 and ALJ-2.

Claimant's Exhibits C-1 through C-3.

Carrier's Exhibits CR-A through CR-H.

DISCUSSION

Claimant, a (Occupation), sustained a compensable lumbar spine injury while he was getting out of a car at work on (Date of Injury). Claimant treated conservatively for his injury at first. Claimant testified that he received epidural steroid injections and has undergone three surgeries,

including laminectomy and fusion with instrumentation. Claimant stated that he also completed a pain management program. Claimant stated that these treatments have helped with his pain, but he is still unable to work, and, without Norco, he is unable to function due to pain. Claimant's current diagnosis is post-laminectomy syndrome, lumbar intervertebral disc displacement and lumbar radiculopathy. On June 4, 2018 a utilization review decision denied the request for Norco because it did not meet established standards of medical necessity. The Independent Review Organization (IRO) upheld the denial.

Claimant testified that he was prescribed Norco in (Year) shortly after his injury. Claimant further testified that he has been prescribed other pain medications in the past, but they were either not as effective or they reacted with his blood pressure medications. Claimant stated that the Norco helps him manage his pain so that he can go on with his life. Claimant's treating doctor, DV, MD, opined that Norco is medically necessary for Claimant. In an appeal letter dated May 29, 2018, Dr. V noted that Claimant has been prescribed Gabapentin, Tramadol and Cymbalta in the past, but these medications were discontinued due to various side effects, including severe nausea, vomiting, tachycardia, dizziness and elevated blood pressure. Dr. V also noted that Dr. JM performed a peer review on December 30, 2015 and determined that Norco is medically necessary.

ZK, MD, performed a required medical examination on December 5, 2016 to determine medical necessity. Dr. K opined that Claimant has been tried on various medications in the past, including NSAIDS, which failed to afford him significant relief. Dr. K further opined that there is no documented evidence of aberrant drug behavior or intolerable side effects and urine drug screens have been consistent. Dr. K concluded that, given these facts, continued use of Norco is necessary and meets the Official Disability Guidelines (ODG) criteria for opioid treatment.

Claimant disagrees with the IRO decision that upheld Carrier's denial and the decision of the utilization review that Norco is not medically necessary treatment. The IRO reviewer, who is board certified in physical medicine and rehabilitation, relied on the Official Disability Guidelines (ODG), the AMA Guides, and on the reviewer's medical judgment, clinical experience and expertise in accordance with accepted medical standards. The reviewer wrote that there was no documentation detailing Claimant's specific subjective and objective findings that would be accounting for a pain condition to support the need for ongoing opioid treatment and there was no documentation of Claimant's pain coping skills ever being addressed and the long-term use of opioids for chronic pain is not supported in the guideline criteria. The reviewer found that Norco 10/325 mg TID #90 is not medically necessary and that weaning is recommended.

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. 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(s), "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."

With regard to NDC – 552890651 NORCO 10/325 MG TID #90, the ODG lists the following criteria:

> 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. (See also Opioids in the *Low Back Chapter*. See *Criteria for Use of Opioids*
>
> Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED). Risks of adverse effects are documented in the literature at doses as low as 50 MED. At this dose of MED, prescribing clinicians should begin to use caution in terms of any additional escalation of dose. At doses of 100 mg MED it is recommended that reassessment of use of this class of drugs should be made due to limited evidence for improved pain control and function

with continued use as well as evidence of substantial adverse risks with higher MEDs. Escalation of doses beyond the 50 to 100 MED range 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. See *Opioid, dosing* for details on how these values were derived based on current literature. 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. 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 this class of drugs there is some evidence that dose reduction does not increase pain levels or decrease function, and in fact, may provide improvement of these outcomes. (*DiBenedetto, 2014*) (*Baron, 2006*) 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. (*McNicol, 2013*)

- *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*)

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 (>100 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. Men taking opioids, especially high doses and over several months, are about 50% more likely to fill a prescription for erectile dysfunction (ED), according to a study of over 11,000 men. (*Deyo, 2013*)

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*) As users of opioids get older, their risk for overdose death increases dramatically. (*Pierce, 2015*) See *Opioid, dosing*.

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*) (*Franklin, 2014*) See *Substance abuse (tolerance, dependence, addiction*). See also *Implantable pumps for narcotics*. According to a major NIH systematic review, there is insufficient evidence to support the effectiveness of long-term

opioid therapy for improving chronic pain, but emerging data support a dose-dependent risk for serious harms. (*Chou, 2015*)

Not recommended except for short use for severe cases, not to exceed 2 weeks. See the *Pain Chapter* for more information and studies.

When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. The studies found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems. (*Bigos, 1999*) Recent studies document a 423% increase in expenditures for opioids for back pain, without demonstrated improvements in patient outcomes or disability rates. (*Deyo, 2009*) With opioid therapy for nonspecific low back pain compared with no opioids, the odds of chronic work loss were six times greater for claimants with schedule II ("strong") opioids; were 11-14 times greater for claimants with opioid prescriptions of any type during a period of ≥90 days; and 3 years after injury, costs of claimants with schedule II opioids averaged $19,453 higher than costs of claimants in the no opioids group. (*Volinn, 2009*) This large study found that prescription of opioids was common among patients with back pain, and increasing duration of opioid use was strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse); almost 50% of patients receiving long-term opioids had at least one of these diagnoses. Similarly, negative health habits (obesity, smoking) were associated with duration of opioid use. The wisdom of long-acting opioid use for chronic pain remains controversial. (*Deyo, 2011*)

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.

After a careful review of all of the evidence presented, Claimant has failed to prove that the preponderance of the evidence based medical evidence is 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. The Texas Department of Insurance, Division of Workers' Compensation has jurisdiction in this matter.

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

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

   D. On (Date of Injury), Employer provided workers' compensation insurance through Texas Property & Casualty Insurance Guaranty Association, Carrier.

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

   F. The Division appointed US Decisions Inc. as the Independent Review Organization (IRO).

   F. The Independent Review Organization determined that claimant should not have NDC – 552890651 NORCO 10/325 MG TID #90.

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 Administrative Law Judge's Exhibit Number 2.

3. NDC – 552890651 NORCO 10/325 MG TID #90 is not health care reasonably required 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 the IRO that NDC – 552890651 NORCO 10/325 MG TID #90 is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

NDC – 552890651 NORCO 10/325 MG TID #90 is not health care reasonably required 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 **TEXAS PROPERTY & CASUALTY INSURANCE GUARANTY ASSOCIATION FOR RELIANCE INSURANCE COMPANY** and the name and address of its registered agent for service of process is

MARVIN KELLY, EXECUTIVE DIRECTOR
9120 BURNET ROAD
AUSTIN, TEXAS 78758

Signed this 11th day of December 2018.

FRANCISCA OKONKWO
Administrative Law Judge