MEDICAL CONTESTED CASE HEARING NO. 14074

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and the Rules of the Texas Department of Insurance, Division of Workers' Compensation. For the reasons discussed herein, the Hearing Officer determines that the claimant is not entitled to continue to receive Hydrocodone/Ibuprofen Tablets 10-200 mg (Reprexain) for the compensable injury on (Date of Injury).

ISSUE

On June 24, 2014, William M. Routon II, a Division hearing officer, held a contested case hearing to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that the claimant is not entitled to continue to receive Hydrocodone/Ibuprofen Tablets 10-200 mg (Reprexain) for the compensable injury on (Date of Injury)?

PARTIES PRESENT

The petitioner/claimant appeared by telephone and was assisted by PA, ombudsman. The carrier/respondent appeared and was represented by DY, attorney.

BACKGROUND INFORMATION

The claimant has undergone several cervical fusion surgeries, the most recent in April, 2013. He complains of chronic neck pain. The claimant came under the care of MN, M.D. as his treating doctor in or about January, 2012. The claimant had first been prescribed Reprexain (a combination of Hydrocodone and ibuprofen) prior to Dr. N becoming his treating doctor, and Dr. N continued that prescription when he began to treat the claimant. Based on the chart documents in evidence from Dr. N, his main function as treating doctor has been to provide to claimant "refills on his medications (xanax and Reprexain)."

Dr. N indicated in his first chart document, in January, 2012, that he placed the claimant on a "controlled substance agreement today as he is receiving narcotics for a period longer than 3 mths[sic]." Dr. N again noted in April, 2012 that the claimant had signed a "CSP Agreement at his last visit." Dr. N also made the claimant submit to a UDS in April, 2012. That UDS was positive for THC according to Dr. N . The claimant was advised by Dr. N that he could not prescribe controlled substances in the presence of illegal drugs. The claimant said he would stop

using THC. Thereafter, through the remainder of the chart documents in evidence from Dr. N , while the CSP Agreement is mentioned occasionally, there is little further mention of any monitoring of the claimant's compliance with the Agreement, and little or no indication of the efficacy of the use of Reprexain. A January, 2013 chart document simply states "UA is negative." In December, 2013, there is a statement in a chart note that the claimant requested increasing his pain medication from 60 pills a month to 90. Dr. N indicated that, "I'm agreeable to this and if this better controlls[sic] his pain we will re-do his CSA on his next visit." It was at about this time that the carrier denied the prescription for the Reprexain (Hydrocodone/ibuprofen). A February, 2014 letter from Dr. N to support the continued, and increased, use of Reprexain stated only that the claimant was being prescribed Hydrocodone/ibuprofen because he was not able to tolerate the Hydrocodone/acetaminophen

In reviewing Dr. N's request for Hydrocodone/Ibuprofen Tablets 10-200 mg (Reprexain), the first utilization review doctor, CK, M.D., initially agreed with the carrier that the prescription should be non-certified, for two primary reasons. The first was that there "was no recent clinical documentation to support deficits that would require medication management," and second, that the Official Disability Guidelines (ODG) did not recommend opioids as a first-line treatment for chronic pain, and there was no indication that the claimant had failed to respond to ODG-accepted first-line treatments. However, Dr. K reversed himself after talking to Dr. N. It was during that conversation that Dr. K was informed that the claimant had tried other medications without success, that the claimant's pain was reduced with the Reprexain, and he was functional with activities of daily living (ADL's) with that medication, and that the claimant had generally had continued efficacy with Reprexain for "the requested dose and quantity for a minimum of two years." However, Dr. K did not certify any refills, apparently for the reason that appears to be the primary complaint of the reviewing doctors, the lack of documentation of the monitoring of the claimant's use and benefit from the Reprexain. Dr. K only certified the use of the Reprexain after talking to Dr. N and receiving the medication management information that is almost completely absent from Dr. N's chart documents.

The utilization review doctor who reviewed the request on reconsideration, board-certified in anesthesiology and by the Board of Interventional Pain Physicians, repeated the concerns of Dr. K that the ODG does not recommend opioids as first-line treatment for chronic pain, and that the "failure of other medication was not documented, it was only noted that the claimant was unable to utilize acetaminophen-containing products because of headaches." He also recommended non-certification.

An IRO reviewer, board certified in family practice, as was Dr. K, upheld the carrier's denial of the Reprexain prescription. The IRO reviewer summarized the concerns of the two utilization reviewers as being that there were minimal records to substantiate the continued use of Reprexain or to document the medication's efficacy, and that there was no indication that the claimant had failed other lines of treatment or other medications for pain. The reviewer added his

own concerns that after the claimant requested an increased prescription for Reprexain in December, 2013, as noted above, there was no documentation that Dr. N followed up to see what extent this had improved the claimant's overall pain level. The reviewer stated that Dr. N's letter in February, 2014 provided no specifics regarding the duration or efficacy of the claimant's use of Hydrocodone. Finally, the reviewer was concerned that there was "no prior documentation regarding compliance testing such as toxicology results of any long term opioid risk assessments which would be indicated for this medication per guidelines."

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 (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 (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."

On the date of this medical contested case hearing, the ODG provides the following with regard to the criteria for use of opioids for chronic pain:

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 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)

(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 difficultly 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)

The primary focus of all of the reviewing doctors was the absence of documentation by Dr. N concerning "**4) On-Going Management**" of the prescription. Dr. N' reports, for the most part, indicated only that he was prescribing Reprexain for the claimant's chronic pain, and that the claimant had signed a controlled substance contract. As the reviewers noted, there was little else in Dr. N' reports as to the efficacy of the medication for claimant's pain, including after the dosage was increased. When this information was provided, one time, in a telephone call, to Dr. K, the Reprexain prescription was certified, although with no refills, apparently based on the one-time disclosure.

A medical doctor is not automatically qualified as an expert on every medical question and an unsupported opinion has little, if any, weight. *Black v. Food Lion, Inc.*, 171 F.3rd 308 (5th Cir. 1999). Health care providers are directed to provide treatment in accordance with the current edition of the ODG, and such treatment is presumed to be reasonably required. (28 Tex. Admin. Code § 137.100 (Rule 137.100)). The documentation of the opioid treatment proposed by Dr. N is not consistent with the directives contained in the current edition of the ODG.

Based on a careful review of the evidence presented in the hearing, the claimant failed to meet his burden of overcoming the IRO decision by a preponderance of the evidence-based medical evidence. The IRO decision in this case is based on the ODG and the evidence revealed that the claimant failed to meet all of the necessary criteria for receiving ongoing prescriptions of Hydrocodone/Ibuprofen Tablets 10-200 mg as set out in the ODG. The preponderance of the evidence-based medicine is not contrary to the decision of the IRO and, consequently, the claimant is not entitled to receive the Hydrocodone/Ibuprofen Tablets 10-200 mg.

The Hearing Officer considered all of the evidence admitted. The Findings of Fact and Conclusions of Law are based on an assessment of all of the evidence whether or not the evidence is specifically discussed in this Decision and Order.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

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

   B. On (Date of Injury), the claimant was the employee of (Employer), Employer.

   C. On (Date of Injury), the claimant sustained a compensable injury.

   D. On (Date of Injury), the employer provided workers' compensation insurance with Nationwide Agribusiness Insurance Company, Carrier.

   E. The IRO determined that the claimant is not entitled to continue to receive Hydrocodone/Ibuprofen Tablets 10-200 mg (Reprexain).

2. The carrier delivered to the claimant a single document stating the true corporate name of the carrier, and the name and street address of the carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. There is insufficient documentation to support the ongoing provision of Hydrocodone/Ibuprofen Tablets 10-200 mg (Reprexain) to the claimant for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Workers' Compensation Division of the Texas Department of Insurance 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 that the claimant is not entitled to continue to receive Hydrocodone/Ibuprofen Tablets 10-200 mg (Reprexain) for the compensable injury on (Date of Injury).

DECISION

The claimant is not entitled to continue to receive Hydrocodone/Ibuprofen Tablets 10-200 mg (Reprexain) for the compensable injury on (Date of Injury).

ORDER

The carrier is not liable for the benefits at issue in this hearing. The claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **NATIONWIDE AGRIBUSINESS INSURANCE COMPANY**, and the name and address of its registered agent for service of process is:

CORPORATION SERVICE COMPANY
211 EAST 7TH STREET, SUITE 620
AUSTIN, TX 78701-3232

Signed this 1st day of July, 2014.

William M. Routon II
Hearing Officer