MEDICAL CONTESTED CASE HEARING NO. 20014

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 Administrative Law Judge (ALJ) determines that Claimant is not entitled to Lyrica 50mg Qty: 28 DS: 28, Tramadol 50mg Qty: 112 DS: 28 and Celebrex 200mg Qty: 28 DS: 28.

STATEMENT OF THE CASE

On September 21, 2020, Britt Clark, a Division ALJ, held a contested case hearing to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the IRO's determination that Claimant is not entitled to Lyrica 50mg Qty: 28 DS: 28, Tramadol 50mg Qty: 112 DS: 28 and Celebrex 200mg Qty: 28 DS: 28?

PARTIES PRESENT

Claimant/Petitioner appeared and was assisted by CT, ombudsman. Carrier/Respondent appeared and was represented by PS, attorney. The parties attended by video conference due to the COVID-19 pandemic.

EVIDENCE PRESENTED

The following witnesses testified:

For Claimant: Claimant.

For Carrier: None.

The following exhibits were admitted into evidence:

ALJ's Exhibit ALJ-1.

Claimant's Exhibit C-1.

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

DISCUSSION

This case involves the medical necessity of multiple medications that have been prescribed for the compensable injury of (Date of Injury). Claimant contested the opinion of the IRO and

contended that the medications at issue were medically necessary to treat pain for the compensable injury. Carrier relied on the opinion of the IRO and the opinions of its Utilization Review (UR) agents.

Texas Workers' Compensation Act: Texas Labor Code §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 Labor Code §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 Labor Code §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. Labor Code §413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Labor Code §413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by 28 TAC §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 Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with 28 TAC §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 Opiate use:

> CRITERIA FOR USE OF OPIOIDS
>
> These criteria do not apply to patients who are prescribed opioids for cancer patients or hospice care.
>
> Steps to take before a therapeutic trial of opioids

a) Determine that the patient has chronic pain, and 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, and other non-pharmacologic modalities.

(c) Before initiating therapy, the patient should set goals (including for pain and function), and the continued use of opioids should be contingent on meeting these goals. Realistic expectations and limitations of opioid treatment should be discussed.

(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. The CDC recommends a 3-item (PEG) Assessment Scale. This includes a pain assessment, a measure of pain interference with enjoyment of life, and a measure of pain interference with general activity (all using a scale of 0-10). (*CDC, 2019*)

(e) A validated opioid risk assessment evaluation should be performed. 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/substance use disorder is important.

(f) Pain related assessment should include history of pain treatment and effect on pain and function. Items to document include duration of symptoms, triggers of pain, locations/radiation of pain, intensity, impact, and patient perception of pain.

(g) The history should also include a list of comorbidities/coexisting disease (including those that are not work related in workers' compensation patients), Diseases that can increase risk of harm from opioids include respiratory conditions, obesity, and renal and/or hepatic insufficiency.

(i) 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.

(j)) An evaluation should be made of indicators 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) Age greater than 65 years. (3) 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 including somatic symptom and related disorders (previously classified as somatoform disorders), anxiety, depression, post-traumatic stress disorder, or history of substance use disorder. It has been suggested that patients may misuse opioids prescribed for pain to obtain relief from depressed feelings, anxiety, insomnia, or discomforting memories.

(k) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function. Important information in this regard can include assessment of psychological factors such as beliefs/expectations related to opioid use.

(l) The prescribing clinician should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian. Specific risks for initiating opioid therapy include active substance-use disorder, elevated suicide risk, and current use of benzodiazepines.

(m) Opioids should not be prescribed at the same time as benzodiazepines. Caution should be used with evidence of other sedative hypnotics (such as sleep aids), muscle relaxants, ante-epilepsy drugs, and/or antidepressants.

(n) Caution should be used in considering opioid therapy in patients who do not participate in other aspects of a comprehensive care plan.

(o) A written consent or pain agreement for chronic use is recommended to document patient education, the treatment plan, and the informed consent.

(p) A urine drug screen should be obtained prior to initiating planned chronic opioid therapy. Items to check for include presence of illicit drugs, and presence of benzodiazepines.

(q) Prescription drug monitoring reports should be obtained prior to initiating opioid therapy. In particular, an evaluation for opioid and other scheduled drug prescriptions from other providers should be obtained.

Therapeutic Trial of Opioids:

Initiating Therapy in Patients Who are Not Currently on Chronic Opioid Therapy

(a) Start with a short-acting opioid at the lowest effective dose, trailing one medication at a time. When initially prescribing, a dose over 50 morphine milligram equivalents (MME) per day is not recommended, with a limit of 90 MME/day considered an upper range of dose unless a higher dose can be justified. As with acute pain recommendations, a consensus opinion is that the initial prescription should be for no longer than 1 week.

(b) 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.

(c) Only change/add 1 drug at a time.

(d) Prophylactic treatment of constipation should be initiated.

(e) Assessment of the trial should include pain and function outcomes, as well as progress towards treatment goals. This should be documented. A LACK OF CLINICALLY MEANINGFUL IMPROVEMENT IN FUNCTION IS A REASON FOR DISCONTINUING OPIOID THERAPY. A 30% improvement in pain and function is considered clinically meaningful. Again, the CDC recommends the 3-item (PEG) Assessment Scale (described above). (*CDC, 2019*)

(f) There should be an assessment of behaviors that could show increased risks of chronic opioid therapy with initiation of therapy. This should include medical complications with use, as well as of indications for potential for substance use disorder (e.g., non-adherence, or other behaviors suggesting opioid use disorder.

On-Going Management:

(a) In all patients, caution should be maintained at a dose of 50 MME/day, particularly in patients taking sedative drugs and/or substances that increase respiratory and central nervous depression (e.g. benzodiazepines, muscle relaxants, sedative hypnotics and/or alcohol).

(b) A limit of 90 MME/day is considered an upper range of dose unless a higher dose can be justified in opioid naïve patients transitioning to chronic opioid therapy. A limit of 90 MME/day should be a goal, with case-by-case exceptions if possible, for patients who have been on chronic high-dose opioids.

(c) Patients on chronic opioid therapy at doses higher than 90 MME/day, and who are physically dependent to this class of drugs, should be offered a tapering plan that emphasizes working collaboratively with the patient. Re-evaluation of the underlying causes of pain, including of causes that are not related to the original etiology for which opioids were prescribed, should be made. Opioid hyperalgesia should be ruled out. Consideration of buprenorphine as a treatment option, with an eventual plan for taper, may be necessary on a case-by-case basis in compliant patients who have been maintained on high doses of opioids for years. Patients should not be abruptly discontinued from their opioids, nor should rapid tapering be undertaken. (*Manhapra, 2018*) (*Kroenke, 2019*) (*HHS, 2019*)

(d) Prescriptions should be from a single practitioner taken as directed, and all prescriptions from a single pharmacy. This can be verified, in part, from prescription drug monitoring reports.

(e) Ongoing assessment should continue to include pain and function outcomes, as well as progress towards treatment goals. This should be documented. A LACK OF CLINICALLY MEANINGFUL IMPROVEMENT IN FUNCTION IS A REASON FOR DISCONTINUING OPIOID THERAPY. A 30% improvement in pain and function is considered clinically meaningful. Again, the CDC recommends the 3-time (PEG) Assessment Scale (described above). (*CDC, 2019*)

(f) Ongoing urine drug testing and Prescription Drug Monitoring is recommended. Random pill counts are also a tool for monitoring.

(g) Ongoing assessment of complications of opioids should be assessed for. These include depression, sleep-disordered breathing, evidence of opioid hyperalgesia, hypogonadism, constipation, sedation, cognitive dysfunction, and immune system dysfunction.

(h) Documentation of factors that may lead to concern, including for potential for misuse should be made. These include the following: non-adherence to the non-medication components of the comprehensive pain care plan; non-adherence with opioid prescribing (e.g., self-escalation/ running out early, taking drugs from outside sources such as family and friends); unexpected drug testing or prescription drug monitoring reports.

(i) Immediate discontinuation has been suggested for the following: evidence of illegal activity including diversion; prescription forgery; the patient is involved in a motor vehicle accident and/or arrest related to opioids; monitoring consistent with 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. Detoxification may be an option on a case-by-case basis.

(j) Immediate attention should be given, with consideration of possible discontinuation, in patients with evidence of substance use disorder, unstable mental health disorder, a medical condition that increases opioid risks, or use of meds (including those introduced after opioids are started) that can increase risk of overdose and death.

(k) Continuing review of overall situation with regard to nonopioid means of pain control.

(l) Consideration of a consultation with a Multidisciplinary treatment if indicated, Multidisciplinary pain programs 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 a substance abuse consult if there is evidence of substance misuse or frank substance use disorder.

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

(a) Visits are recommended as frequently as 1 to 2 weeks for the first 1 to 2 months of therapy.

(b) Ongoing follow up can be extended to up to 3 months. Federal law requires a visit must occur at least every 3-month basis for refills of Schedule II drugs.

When to Consider Tapering to Reduced Dosage or Tapering and Discontinuing Opioid:

See Opioid hyperalgesia. Also see Opioids, weaning of medications.

(a) If there is no overall improvement or actual decrease in pain, function, and quality of life, unless there are extenuating circumstances.

(b) Continuing pain with the evidence of intolerable adverse effects; lack of significant benefit (persistent pain, decreased quality of life, and lack of improved function despite high doses of opiates- e.g. > 90 MME/day)

(c) Resolution of pain

(d) If serious non-adherence is occurring.

(e) The patient requests reduction or discontinuing.

(f) The patient experiences an overdose or other serious event such as hospitalization as related to opioid use.

(g) The patient has warning signs of an impending serious event such as overdose, including confusion, sedation, or slurred speech.

(h) There is evidence of the addition of medications to the patient's medication regimen which increase risk of overdose and death (in particular benzodiazepines), or has developed a medical disease or condition which puts him/her at risk for adverse outcomes (e.g. lung disease, sleep apnea, liver disease, kidney disease, fall risk, or advanced age).

i) The patient has been treated with opioids for a prolonged period (in some cases years), and risk-benefit of use is unclear.

(j) 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. It is strongly recommended to not abandon a patient if possible.

(k) 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.

(l) 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 substance use disorder to assess the ongoing situation and recommend possible detoxification.

(m) 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.

When to Continue Opioids

(a) If the patient has returned to work.

(b) If the patient has improved functioning, quality of life, and pain. (*Dowell, 2019*) (*VA/DOD, 2017*) (*Rosenberg, 2018*) (*Manhapra, 2018*) (*Kroenke, 2019*) (*HHS, 2019*) (*Moride, 2019*)

The IRO reviewer agreed with two UR doctors and opined that the requested medications did not meet ODG criteria. Specifically, the IRO reviewer opined that Claimant had a lack of clinically meaningful improvement of function attributable to the medications, with a lack of 30% improvement in pain documented in the medical records. The IRO review cited the lack of information submitted by the provider to indicate how these medications were improving Claimant's pain levels and function to justify ongoing use. The two UR doctors opined there was limited clinical and objective findings to show functional improvement from the requested medications. Claimant provided the medical records from Dr. DG as well as some other medical providers. Dr. G addressed the denial of medication and stated that Claimant's pain has been well-controlled over time. However, Dr. G and the other records do not address the lack of functional improvement discussed by the IRO doctor and the UR doctors. There was a lack of a persuasive explanation from Claimant's medical providers as to how these medications meet ODG criteria or how they are consistent with other evidence-based medicine.

Claimant has the burden of proof on this case to show by the preponderance of evidence-based medical evidence that the medications are clinically appropriate and considered effective for his injury. Evidence-based medical evidence entails the opinion of a qualified expert that is supported by evidence-based medicine. The evidence presented at the hearing cannot be construed to constitute evidence-based medical evidence sufficient to overcome the decision of the IRO reviewer. As Claimant did not overcome the IRO decision by a preponderance of the evidence-based medical evidence, he has accordingly failed to meet his burden of proof.

The ALJ 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 Texas Department of Insurance, Division of Workers' Compensation.

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

C. On (Date of Injury), Employer provided workers' compensation insurance through American Home Assurance Company, which is now being provided through New Hampshire Insurance Company, Carrier.

D. On (Date of Injury), Claimant sustained a compensable injury.

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 Carrier's Exhibit G.

3. Lyrica 50mg Qty: 28 DS: 28, Tramadol 50mg Qty: 112 DS: 28 and Celebrex 200mg Qty: 28 DS: 28 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 Claimant is not entitled to Lyrica 50mg Qty: 28 DS: 28, Tramadol 50mg Qty: 112 DS: 28 and Celebrex 200mg Qty: 28 DS: 28.

DECISION

Claimant is not entitled to Lyrica 50mg Qty: 28 DS: 28, Tramadol 50mg Qty: 112 DS: 28 and Celebrex 200mg Qty: 28 DS: 28.

ORDER

Carrier is not liable for the benefits at issue in this hearing, and it is so ordered. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **NEW HAMPSHIRE 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 78701-3218

Signed this 23rd day of September, 2020.

BRITT CLARK
Administrative Law Judge