MEDICAL CONTESTED CASE HEARING NO. 14080

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 Hearing Officer determines that Claimant is entitled to Nucynta 100 mg, 1 tablet, three times per day, quantity 90 for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

A contested case hearing was held on July 22, 2014 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 Nucynta 100 mg, 1 tablet, three times per day, quantity 90 for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by VS, ombudsman.
Respondent/Carrier appeared and was represented by JL, attorney.

BACKGROUND INFORMATION

Claimant, a nurse practitioner, testified that she injured her right foot on (Date of Injury) when she and a co-worker were transporting a patient to another floor. Claimant testified that the patient was in a hospital bed and, as they were entering the elevator, the co-worker accidently rolled the bed onto her right foot. Claimant sustained fractures of the second and third metatarsals and the fifth metatarsal was dislocated. Claimant underwent surgery on her right foot. Claimant was prescribed various medications for her condition, but she continued to experience pain and hypersensitivity in her right foot. Claimant was eventually diagnosed with reflex sympathetic dystrophy/complex regional pain syndrome.

Claimant came under the care of pain management specialist Dr. JC on September 13, 2011. When he evaluated Claimant on September 13, 2011, Dr. C recommended that she begin taking Nucynta 50 mg, one to two tablets, three times per day for symptoms related to her complex regional pain syndrome. Dr. C's medical records indicate that he prescribed for Claimant a combination of Nucynta 50 mg and Nucynta ER 250 mg. However, on May 17, 2012 he changed the Claimant's prescription to Nucynta 100 mg, 1 tablet three times per day, quantity 90. His records indicate that the combination of Nucynta and Nucynta ER was not working well. The medical records indicate that Claimant has been taking Nucynta 100 mg since May 2012.

On January 7, 2014, a request for Nucynta 100 mg, 1 tablet three times per day, quantity 90 was received by the Carrier from Dr. C. On January 10, 2014, Carrier's utilization review agent (URA) denied Dr. C's request because Nucynta is a second-line opioid and there was no documentation of intolerable adverse effects with first-line opioids. A request for reconsideration was submitted on January 22, 2014. A second URA denied Dr. C's request for Nucynta for the same reasons as the first URA.

Claimant appealed the Carrier's decision to an IRO. The IRO upheld the Carrier's denial. The IRO stated that "the clinical documentation submitted for review does not identify clear functional improvement or pain reduction with the continuing use of Nucynta to warrant its ongoing use." Claimant appealed the IRO decision to this Medical Contested Case Hearing.

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 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 is considered a party to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has

the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

With regard to Nucynta, the ODG provides as follows:

> Recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. These recent large RCTs concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations. (Afilalo, 2010) (Buynak, 2010) (Lange, 2010) On November 21, 2008, the FDA approved tapentadol immediate-release tablets for relief of moderate to severe acute pain. Tapentadol, manufactured by Johnson & Johnson Pharmaceutical, is a new centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. (Johnson, 2008) Nucynta™ (tapentadol) was made a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. Nucynta™ may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. (FDA, 2009) Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone, so if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be recommended as a second-line choice. (Daniels, 2009) (Daniels2, 2009) (Hale, 2009) (Hartrick, 2009) (Stegmann, 2008) Gastrointestinal adverse events led to discontinuation in 9% of the tapentadol group versus 22% of the oxycodone group. (Wild, 2010) This review questioned the opioid potency of tapentadol, and suggested that it affects pain modulation through inhibition of norepinephrine. (Prommer, 2010) But the manufacturer disagrees. (Nelson, 2011) In August 2011 FDA approved tapentadol extended release (Nucynta ER) for moderate to severe chronic pain. Nucynta was already approved for acute pain. (FDA, 2011)

Claimant testified that she has tried multiple medications for pain control that have not been very effective or that have caused intolerable side effects. Claimant testified that for the past two years she has been taking Ultram and Nucynta 100 mg, as prescribed by Dr. C, and the combination allows her to work full time. Claimant testified that her primary care physician, Dr. MH, will occasionally prescribe Norco with the permission of Dr. C. Claimant testified that she does have some pain, but her condition has been stable and she has not had to escalate her medications. Claimant's testimony regarding her medical history and the effects of her medications on her condition was credible.

Claimant also relies on the testimony of Dr. H to support her position on the disputed issue. Dr. H has been Claimant's primary care physician for several years. She began seeing Claimant prior to her work-related injury. Dr. H is also Claimant's current employer. Dr. H reviewed the IRO opinion and stated that it did not appear that the IRO reviewed any of Claimant's medical records prior to 2011 and was unaware of the first line medications that Claimant took for her injury. Therefore, she believed the IRO's opinion was based on incomplete information. Dr. H stated that her opinion is based on a complete understanding of Claimant's history and her medical knowledge concerning Claimant's diagnosis.

Dr. H testified that the Claimant meets the criteria outlined in the ODG regarding the use of Nucynta. She testified that Claimant has neuropathic pain syndrome and it is a chronic condition. Dr. H testified that Claimant has been on a number of first line medications for her injury. She acknowledged that she has prescribed some medications for Claimant's work-related injury. Dr. H testified that a combination of Lyrica, Neurontin, and Elavil is usually prescribed for neuropathic pain. According to Dr. H, Claimant was on those medications, but the combination of medications caused mental status changes in Claimant. She said Claimant had trouble focusing. Dr. H testified that Claimant's current combination of medications, Ultram and Nucynta, helps her to focus at work.

Dr. H persuasively established through her testimony the medical necessity of the Nucynta. In particular, Dr. H's testimony demonstrated that the use of the medication is supported by the ODG. As a preponderance of the evidence-based medical evidence is found to outweigh the determination of the IRO on the medical necessity of the medication in this case, Claimant is held to be entitled to Nucynta 100 mg, 1 tablet, three times per day, quantity 90 as health care reasonably required for the compensable injury of (Date of Injury).

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 Texas Department of Insurance, Division of Workers' Compensation.

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

   C. Claimant sustained a compensable injury on (Date of 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 Hearing Officer's Exhibit Number 2.

3. The medication Nucynta is 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 medical evidence is contrary to the decision of the IRO that Nucynta 100 mg, 1 tablet, three times per day, quantity 90 is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is entitled to Nucynta 100 mg, 1 tablet, three times per day, quantity 90 for the compensable injury of (Date of Injury).

ORDER

Carrier is liable for the benefits at issue in this hearing. Claimant also remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **SENTRY INSURANCE A MUTUAL COMPANY** and the name and address of its registered agent for service of process is:

CT CORPORATION SYSTEM
1999 BRYAN STREET, STE. 900
DALLAS, TX 75201

Signed this 8th day of August, 2014.

Jacquelyn Coleman
Hearing Officer