MEDICAL CONTESTED CASE HEARING NO. 15012

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 the preponderance of the evidence is not contrary to thte decision of the Independent Review Organization (IRO) that Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month 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 November 18, 2014, 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 Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by EB, ombudsman. Respondent/Carrier appeared and was represented by GS, attorney.

EVIDENCE PRESENTED

The following witnesses testified:

For Claimant: Claimant.

For Carrier: Dr. WN.

The following exhibits were admitted into evidence:

Hearing Officer's Exhibits HO-1 through HO-2.

Claimant's Exhibits C-1 through C-7.

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

BACKGROUND INFORMATION

On (Date of Injury), Claimant injured his right knee and low back while carrying a handrail at work. On January 12, 2006, Claimant underwent a right knee ACL repair and partial medial

meniscectomy. Postoperatively he had complications with pain and stiffness and underwent several additional arthroscopic and manipulation procedures to restore motion and function. Claimant was referred to Dr. MB for pain management. Claimant developed complex regional pain syndrome (CRPS/reflex sympathetic dystrophy (RSD)) related to his right knee injury. The RSD has spread from the right lower extremity to the left lower extremity and into both upper extremities. Dr. B has seen Claimant on a monthly and more frequent basis and has prescribed numerous medications including Opana ER, Lidoderm 5% patch, Lunesta 3 mg for sleep, Lyrica 25 mg two twice a day, Soma 350 mg three times a day and hydrocodone/acetaminophen 10/325 mg up to three times a day for breakthrough pain. Claimant was first prescribed Opana on November 25, 2009 and the dosage of Opana ER has over the past five years been increased from 10 mg every 12 hours to 40 mg every 12 hours. Claimant has declined insertion and use of a spinal cord stimulator or morphine pump. On April 24, 2014, an appeal for Opana ER 40 mg taken once every 12 hours for a quantity of 60 per month was received by the Carrier from Dr. B. On April 29, 2014, Carrier's utilization review agent (URA) denied Dr. B's request. A request for reconsideration was denied on May 14, 2014, by another URA. The dispute was presented to an IRO doctor who determined on June 18, 2014, based on the Official Disability Guidelines (ODG) and medical judgment, that there was a lack of documentation showing decreased pain and/or increased functionality and thus the continued use of Opana was denied as medically necessary.

DISCUSSION

Texas Labor Code Section 408.021 provides 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 that evidence 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, by 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 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 Opana ER, Appendix A, ODG Workers' Compensation Drug Formulary (As of March 31, 2014) lists it as an "N" drug that requires preauthorization. The ODG provides as follows:

> "Oxymorphone (Opana) Not recommended. See Opioids for general guidelines, as well as specific Oxymorphone (Opana®) listing for more information and references. Due to issues of abuse and Black Box FDA warnings, Oxymorphone is recommended as second line therapy for long acting opioids. Oxymorphone products do not appear to have any clear benefit over other agents and have disadvantages related to dose timing (taking the IR formulation with food can lead to overdose), and potential for serious adverse events (when the ER formulation is combined with alcohol use a potentially fatal overdose may result). (Opana FDA labeling)"

Specifically, the ODG treatment guidelines relevant to the medication at issue shows:

> **"Oxymorphone** *(Opana®), Oxymorphone Extended Release (Opana ER®), available generic available:* **[Boxed Warnings]:** Opana ER® is not intended for prn use. Patients are to avoid alcohol while on Opana ER® due to increased (possibly fatal) plasma levels. *Side Effects:* See opioid adverse effects. Immediate release and extended release tablets should be taken 1 hour before or 2 hours after eating. *Analgesic dose:* (Immediate release) in opioid-naive patients the starting dose is 10-20mg PO every 4 to 6 hours as needed. Patients may be started at doses of 5mg if appropriate (e.g., renal impairment). Refer to full prescribing information for calculating conversions from other opioids. Note: It is not recommended to begin therapy at doses higher than 20mg due to adverse effects. (Extended release tablets) Opioid-naive patients should initially begin on 5mg every 12 hours around the clock. It is recommended that doses be individually titrated in increments of 5 to 10mg every 12 hours for 3 to 7 days. (Product information, Ethex Pharmaceuticals)"

This medication refers the reader to "Opioids" in the ODG. Below is an applicable section from the ODG for Opioids:

“CRITERIA FOR USE OF OPIOIDS:

Long-term Users of Opioids (6-months or more)

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)"

Claimant testified that he was happier with his pain control when he was allowed to take this medication in 10 mg doses, multiple times a day. Claimant denied any abuse or aberrant drug-taking behavior due to his usage of Opana ER. In support of Claimant's position were the April 3, 2013, July 22,2 013, and May 27, 2014, letters of medical necessity by Dr. B, emphasizing Claimant's need for the continued use of the medication. Carrier offered the report and testimony by Dr. WN in support of the IRO's decision. Dr. N explained that Claimant's established treatment regimen exceeds the 120 mg of oral morphine equivalent limits as established by the ODG, and Claimant should be weaned from the medication as recommended in the ODG.

Dr. N was persuasive in reporting that Claimant's total daily opioid intake was close to three times the recommended dose. There was no documentation in the medical records of a periodic measurement of function or objective evidence noted of functional improvement with use of Opana ER. Even though the May 27, 2014, letter from Dr. B criticized the IRO's decision, the requirements of the ODG relating to treatment options and functional improvement documentation with opioids usage were not met. Claimant did not meet his burden of proof to show that the preponderance of evidence-based medical evidence was contrary to the IRO decision.

The Hearing Officer considered all of the evidence submitted. 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 the 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), Claimant sustained a compensable injury.

   D. The Independent Review Organization determined Claimant was not entitled to Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month for the compensable injury of (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. Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month 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 Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to Opana ER 40 mg 1 tablet by mouth every 12 hours #60 per month 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 **SENTRY INSURANCE A MUTUAL COMPANY,** and the name and address of its registered agent for service of process is

CT CORPORATION
1999 BRYAN STREET, SUITE 900
DALLAS, TEXAS 75201.

Signed this 21st day of November, 2014.

Judy L. Ney
Hearing Officer