MEDICAL CONTESTED CASE HEARING NO. 16001

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 not entitled to Butrans patches 10mcg for the compensable injury of (Date of Injury)

STATEMENT OF THE CASE

On September 22, 2015, a medical contested case hearing was held 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 Butrans patches 10mcg for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant and his wife, JW, appeared by phone and were assisted by TB, ombudsman. Respondent/Carrier appeared and was represented by JF, attorney.

BACKGROUND INFORMATION

Claimant sustained a compensable injury on (Date of Injury). His doctor is currently treating him for chronic pain associated with his compensable injury. His doctor, LR, MD., recommended Claimant be treated with Butrans patches 10mcg. Carrier disputed the need for this medication. Carrier's two utilization review doctors opined this medication was not reasonable or medically necessary. Claimant's doctor disputed their determinations and requested an Independent Review Organization (IRO) review. The IRO doctor, who is board certified in physical medicine and rehabilitation and pain medicine upheld Carrier's denial. Claimant requested a medical contested case hearing, disputing the finding of the IRO doctor.

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."

On the date of this medical contested case hearing, the ODG provides the following with regard to Butrans patches 10mcg (buprenorphine):

> Recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). *Suggested populations:* (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience.
>
> *Drug description:* Buprenorphine is a schedule-III controlled substance. Its mechanism of action is complex, involving four different opioid receptors at central and peripheral sites. It is primarily classified as a partial mu-agonist and kappa antagonist. It blocks effects of subsequently administered opioid agonists.
>
> *Proposed advantages of treatment:* (1) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor); (2) Ability to suppress opioid withdrawal; (3) Indications of safety for use in patients with renal impairment.

There appears to be a ceiling effect for respiratory depression. (Johnson, 2005) (Koppert, 2005) (Pergolizzi, 2008) (Malinoff, 2005) (Landau, 2007) (Kress, 2008) (Heit, 2008) (Helm, 2008) (Silverman, 2009) (Pergolizzi, 2010) (Lee, 2011) (Rosenblum, 2012) (Daitch, 2012) (Colson, 2012) See also Opioid hyperalgesia.

Treatment of chronic pain: A waiver is not required for the off-label use of sublingual buprenorphine for the treatment of pain. An "X" should NOT be put before the DEA number. It is recommended that the words, "Chronic Pain Patient" and "Off-Label Use" be written on the prescription. The most common use of buprenorphine formulations other than Butrans (such as Suboxone) for the treatment of chronic pain is for individuals who have a history of opioid addiction.

Use in opioid-experienced patient: There is the potential for buprenorphine to precipitate withdrawal in opioid-experienced patients.

Available formulations:

Buprenorphine hydrochloride injection (Buprenex®; generics available).

Buprenorphine hydrochloride sublingual tablets (Subutex® [innovator brand is off market]; generics available): 2 mg and 8 mg.

Buprenorphine hydrochloride and naloxone hydrochloride sublingual film (Suboxone®; no generics): Available as a film in doses of buprenorphine/ naloxone of 2mg/0.5mg, 4mg/1 mg, 8mg/2 mg and 12mg/3 mg. Tablet formulations are available as 2mg/0.5mg and 8mg/2mgs. Discontinuation of branded Suboxone sublingual tablets is to occur on 3/18/13, being replaced by the sublingual film described above.

Buprenorphine transdermal system (Butrans®; no generics): FDA-approved for moderate to severe chronic pain. Available as transdermal patches at 5mcg/hr, 10mcg/hr and 20mcg/hr.

The IRO doctor wrote the following regarding this medication:

It may be recommended for selected patients who have previously been detoxified from other high dose opiates and who have a hyperalgesic component to pain or centrally mediated pain or neuropathic pain of it the patient is at high risk of non-adherence with standard opiate maintenance…. The 03/06/15 letter of medical necessity states this is being used as a titration from hydrocodone and it was noted the specific period of time requested for treatment was 99 months or longer. This

> has not been clarified. The patient was still on opiates per the drug screen and the records do not therefore document the patient had been detoxified. Therefore rationale for this drug at this time has not been documented.

The IRO doctor went right down the line of the first paragraph of the ODG, noting which patients this medication is recommended for. The IRO doctor noted the lack of documentation in the medical records indicating Claimant has been detoxified.

Carrier utilized two peer reviews in its utilization review process. The first utilization doctor, TA, M.D., tried calling Dr. R twice and left messages both times that apparently went unreturned. He noted a letter from Dr. R dated March 09, 2015, that indicated this medication was being used as a titration from hydrocodone for 99 months or longer. He noted there were no clinical records submitted for review. Dr. A wrote that "there are no submitted/available clinical medical records and therefore no information regarding rationale for the medication, mechanism of injury, body parts involved, past workup and treatment, (and) current symptoms." He noted that the notation that this medication would be used for 99 months or longer contradicted the comment on the letter that this medication was being used to titrate Claimant off hydrocodone, and that this contradiction needed to be clarified. Dr. A recommended against the prescription.

The second utilization review doctor, AB, M.D., tried to contact Dr. R, but she did not return his calls. In short, he wrote that the medication was not being certified due to the lack of medical documentation or clinical information to support the certification. He lists as the records he reviewed as the peer review by Dr. A, the March 15, 2015, letter of medical necessity and a medication list. He noted, "[D]ocumentation is still lacking objective deficits and the ODG opioid compliance guidelines including a risk assessment profile, attempt at weaning/tapering, an updated urine drug screen, and an updated and signed pain contract between the claimant and provider." He wrote that considering the lack of clinical information and Dr. R not complying with the ODG, the medical necessity for this medication was not established. He then wrote what was needed for this medication to be certified.

There is a lack of clinical information or objective medical documentation in evidence to support Claimant's position. Claimant provided one document, reportedly signed by Dr. R and apparently dated (by hand) on March 23, 2015. The March 06, 2015, and March 15, 2105, letters are not in evidence and no clinical records are in evidence. The March 23, 2015, document does not state anything more than what the other two letters reviewed by Dr. A and Dr. B apparently noted. Dr. R does not address the ODG and does not indicate if Claimant is one of the enumerated patients Butrans patches are recommended to treat. She does not indicate if Claimant is a patient with a hyperalgesic component to pain; centrally mediated pain; neuropathic pain; at high-risk of non-adherence with standard opioid maintenance; or for analgesia because Claimant has been detoxified from other high-dose opioids. The ODG does not say this medication is used to titrate patients off hydrocodone.

Petitioner did not show by a preponderance of the evidence-based medicine that the proposed care is health care reasonably required for the compensable injury.

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. 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 doctor board certified in physical medicine and rehabilitation and pain medicine determined Claimant should not have Butrans patches 10mcg.

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. Butrans patches 10mcg 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 Butrans patches 10mcg is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to Butrans patches 10mcg 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 **BANKERS STANDARD INSURANCE COMPANY** and the name and address of its registered agent for service of process is

CT CORPORATION SYSTEM
1999 BRYAN STREET, SUITE 900
DALLAS, TEXAS 75201-3136.

Signed this 24th day of September, 2015.

KEN WROBEL
Hearing Officer