MEDICAL CONTESTED CASE HEARING NO. 16057

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 the decision of the IRO that the Claimant is not entitled to intrathecal pain pump refill.

ISSUES

A contested case hearing was held on January 31, 2017, to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the IRO that the Claimant is not entitled to an intrathecal pain pump refill?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by KP, ombudsman. Respondent/Carrier appeared and was represented by SS, attorney.

EVIDENCE PRESENTED

The following witnesses testified:

For Claimant: Claimant.

For Carrier: None.

The following exhibits were admitted into evidence:

> Hearing Officer's Exhibits HO-1 through HO-3.
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> Claimant's Exhibits C-1 through C-8.
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> Carrier's Exhibits CR-A through CR-D.

BACKGROUND INFORMATION

Claimant sustained a compensable injury on (Date of Injury), when he was working as a floor installer, and was helping two co-workers pull a pallet jack loaded with tile up an incline when he sustained a compensable thoracic and lumbar spine injury. A Contested Case Hearing was held on December 1, 2003, and the compensable injury was determined to include a thoracic and lumbar spine injury. Claimant has undergone continuous treatment for his compensable injuries

since 2002, including surgery, multiple epidural steroid injections, spinal cord stimulation, and finally an intrathecal pain pump was placed, which provided him the best pain relief of any of the treatments thus far. From 2004 through the Independent Review Organization (IRO) denial, Claimant has received regular intrathecal pain pump refills for his pain management.

Claimant's pain management doctor, BG, M.D., requested an intrathecal pain pump refill on July 13, 2016. The Utilization Review (UR) physician attempted a peer-to-peer contact on July 15, 2016 at 9:15 a.m., and again at 10:35 a.m., though they were informed that Dr. G required 24 hour notice for peer reviews. The UR determined the refill was not supported for two reasons: first, Claimant's pain score was consistently 8/10 while on the pump, which is not indicative of great therapeutic benefit. Second, Dr. G was refilling the pump days before it was required, specifically, the last refill was done two weeks early, so 1/5 of the medication was removed prior to refill. The IRO decision upheld the previous denial, and Claimant appealed.

Claimant testified that the intrathecal pain pump provided him enough relief to allow him to perform additional activities of daily living. He stated that going from a pain level of 10/10 to 8/10 is significant for him, though both are very high pain levels. He further testified his doctor refilled his pain pump early as his doctor believed the pain medications lost all effectiveness at 101 days, so his doctor refilled when he felt the medication was not as effective as it should be. That required removal of old medication, which was not providing the same level of relief due to loss of efficacy, prior to refilling the pump.

Carrier argued the IRO determination was supported by the medical evidence.

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 (t), "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."

The ODG provides the following guidelines concerning Pain (chronic):

ODG Pain (Chronic) – Implantable Drug-Delivery Systems

Indications for Implantable drug-delivery systems:

- *Implantable infusion pumps* are considered medically necessary when used to deliver drugs for the treatment of:
  - Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents);
  - Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents);
  - Head/neck cancers (intra-arterial injection of chemotherapeutic agents);
  - Severe, refractory spasticity of cerebral or spinal cord origin in patients who are unresponsive to or cannot tolerate oral baclofen (Lioresal®) therapy (intrathecal injection of baclofen)

- *Permanently implanted intrathecal (intraspinal) infusion pumps* for the administration of opioids or non-opioid analgesics, in the treatment of chronic intractable pain, are considered medically necessary when:
  - Used for the treatment of *malignant (cancerous) pain* and all of the following criteria are met:
    - Strong opioids or other analgesics in adequate doses, with fixed schedule (not PRN) dosing, have failed to relieve pain or intolerable side effects to systemic opioids or other analgesics have developed; and

- Life expectancy is greater than 3 months (less invasive techniques such as external infusion pumps provide comparable pain relief in the short term and are consistent with standard of care); and
- Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and
- No contraindications to implantation exist such as sepsis or coagulopathy; and
- A temporary trial of spinal (epidural or intrathecal) opioids has been successful prior to permanent implantation as defined by a 50% reduction in pain. A *temporary* trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met.

- Used for the treatment of *non-malignant (non-cancerous) pain* with a duration of greater than 6 months and all of the following criteria are met and documented by treating providers in the medical record:

  - Non-opioid oral medication regimens have been tried and have failed to relieve pain and improve function (see functional improvement); and
  - At least 6 months of other conservative treatment modalities (injection, surgical, psychologic or physical), have been ineffective in relieving pain and improving function; and
  - Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, physical examination and diagnostic testing); and
  - Further surgical intervention or other treatment is not indicated or likely to be effective; and
  - Independent psychological evaluation has been obtained and evaluation states that the pain is not primarily psychologic in origin, the patient has realistic expectations and that benefit would occur with implantation despite any psychiatric comorbidity; and
  - No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and
  - There has been documented improvement in pain and function in response to oral opioid medications but intolerable adverse effects preclude their continued use; and
  - A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by at least a 50% to 70% reduction in pain and documentation in the medical record of functional improvement and associated reduction in oral pain medication use. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-7 above are met.

- For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

- If treatment is determined to be medically necessary, as with all other treatment modalities, the efficacy and continued need for this intervention and refills should be periodically reassessed and documented.

Medications for IDDS if determined to be medically necessary:

First stage: Morphine is generally the initial IDDS medication. The maximum recommended dose for this drug is 15 mg/day with a concentration of 20 mg/mL. An alternative non-FDA approved medication is hydromorphone. The maximum recommended dose for this medication is 4 mg/day with a concentration of 10 mg/mL. Other opioids (including Fentanyl and Sufentanil) have been used for intrathecal chronic non-malignant pain but are non-FDA approved and have little research associated with their use. (*Waara-Wolleat, 2006*) (*Deer, 2007*) The previous 2003 Polyanalgesic conference recommended a maximum dose of intrathecal morphine at 15 mg/day with a maximum concentration of 30 mg/mL. They also recommended a maximum dose of hydromorphone of 10 mg/day with a concentration of 30 mg/mL. (*Hassenbusch, 2004*) The newer maximum concentrations were recommended, in part, to prevent granulomas.

Second stage: If side effects occur, an upper limit of dosing is reached, or neuropathic pain is present, clonidine is next recommended as an addition to an opioid (maximum recommended dose of 1 mg/day and a concentration of 2 mg/mL). Bupivacaine has also been recommended as an alternative to clonidine (maximum dose of 30 mg/day and a concentration of 40 mg/mL). Clonidine, which is FDA approved for intrathecal delivery, is thought to provide analgesic effect via a non-opioid mechanism. It has been found to offer only short-term relief when used as a single agent. (*Deer, 2007*)

Third stage: The recommendation has been made to add both clonidine and bupivacaine. Baclofen has been used to treat intractable spasticity from brain injury, cerebral palsy, and spinal cord injury and has resulted in improvement in muscle tone and pain relief. (*Guillaume, 2005*) See also Ziconotide (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid).

Refills: IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall

> important information about the prescription. (*Hassenbusch, 2004*) According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (*FDA, 2010*) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17 mL have been infused, and most pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20 mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2–3 months. (*Bennett, 2000*)

The IRO doctor, a physician who holds a board certification in Anesthesiology with a sub-certification in Pain Medicine, determined Claimant did not meet the recommended criteria of intrathecal pain pump refill as per ODG. The Claimant reported his pain level was 8/10 in December 2015, January 2016, and April 2016, suggesting no improvement in the pain level with the usage of the intrathecal pain pump. The IRO doctor continued by stating ongoing usage of the intrathecal pain pump has failed to document any effectiveness of the intrathecal pain pump, and is not generating appropriate analgesia. Documentation of functional improvement is necessary in order to justify continued treatment. The IRO doctor further noted that a refill of intrathecal pain pump would not be supported in this clinical situation. Therefore, based on the ODG as well as clinical documentation, the request of intrathecal pain pump refill was not medically necessary or appropriate, as determined by the IRO doctor.

Claimant testified there was a 20% decrease in his pain when the intrathecal pain pump was utilized. Other medications have not provided him that level of relief, and considering his pain level when not using the intrathecal pain pump, a 20% improvement provides him enough relief to be able to function somewhat. In reviewing the medical records, though his pain reports show 8/10 pain levels at each visit, Claimant reported at least 50% relief in his typical low back pain through the infusion of hydromorphone. While it is apparent from the medical records, and Claimant's credible testimony, that Claimant suffers a high degree of pain from significant compensable injuries, and his doctors have regularly recommended the use of an intrathecal pain pump to provide him some amount of relief, there was a lack of persuasive explanation or evidence, citing the ODG treatment guidelines or any other evidence based medical evidence to support Claimant's position.

There was no objection to the testimony, reports, or qualifications of any doctor.

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. The Texas Department of Insurance, Division of Workers' Compensation has jurisdiction to hear this matter.

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

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

   D. On (Date of Injury), Employer provided workers' compensation insurance with Sierra Insurance Company of Texas, Carrier.

   E. On (Date of Injury), Claimant sustained a compensable lumbar and thoracic injury.

   F. The Independent Review Organization determined Claimant was not entitled to intrathecal pain pump refill.

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 decision of the IRO that Claimant is not entitled to intrathecal pain pump refill for the compensable injury of (Date of Injury), is not contrary to the preponderance of evidence.

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 the Claimant is not entitled to intrathecal pain pump refill.

DECISION

The preponderance of the evidence is not contrary to the decision of the IRO that the Claimant is not entitled to intrathecal pain pump refill.

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 Section 408.021 of the Act.

The true corporate name of the insurance carrier is **SIERRA INSURANCE COMPANY OF TEXAS**, and the name and address of its registered agent for service of process is

C T CORPORATION SYSTEM
1999 BRYAN STREET, SUITE 900
DALLAS, TEXAS 75201-3136

Signed this 7th day of February, 2017.

Amber Morgan
Hearing Officer