MEDICAL CONTESTED CASE HEARING NO. 19010

DECISION AND ORDER

This case is decided pursuant to 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 determines that the preponderance of the evidence is not contrary to the decision of the Independent Review Organization that a repeat intrathecal pump trial 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 August 6, 2019, to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that a repeat intrathecal pump trial is not health care reasonably required for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by DS, ombudsman.

Respondent/Carrier appeared and was represented by DM, attorney.

EVIDENCE PRESENTED

The following witnesses testified:

For Claimant: RD.
Dr. GA

For Carrier: None.

The following exhibits were admitted into evidence:

Administrative Law Judge's Exhibits: ALJ-1 and ALJ-2.

Claimant's Exhibits: C-1 through C-6.

Carrier's Exhibits: CR-A and CR-J.

DISCUSSION

Claimant sustained a compensable injury on (Date of Injury), when a steel plate fell on his right hand. The compensable injury of (Date of Injury), extends to and includes complex regional pain syndrome (CRPS). Claimant has received medications and a spinal cord stimulator. Claimant testified that the pain has persisted. Dr. GA recommended a lumbar intrathecal pump.

A Utilization Review was conducted by physician reviewer, Dr. EA, who reviewed the necessity of the repeat intrathecal pump considering the Official Disability Guidelines (ODG) and denied authorization.

Claimant appealed the denial and an Independent Review Organization (IRO) was appointed by the Texas Department of Insurance in accordance with Rule 133.308. After consideration of the information provided, in IRO Case # 251933, the IRO upheld Carrier's denial of the repeat intrathecal pump. Claimant thereafter filed a request for a contested case hearing as provided for by Rule 133.308(s). The contested case hearing was held on August 6, 2019.

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 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 in making decisions about the care of individual patients. 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 adopted treatment guidelines by Division Rule 137.100. The 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 Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. A decision issued

by an IRO is not considered an agency decision and the Department and the Division are not considered parties to an appeal. In a contested case hearing, the party appealing the IRO decision has the burden of overcoming the decision issued by the IRO by a preponderance of the evidence-based medical evidence. (Rule 133.308 (s).)

For the intrathecal pump, the ODG lists the following criteria:

> Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated in the blue criteria below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial.
>
> 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:
>
> (1) 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
>
> (2) 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
>
> (3) Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and

(4) No contraindications to implantation exist such as sepsis or coagulopathy; and

(5) 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:

(1) Non-opioid oral medication regimens have been tried and have failed to relieve pain and improve function (see functional improvement); and

(2) At least 6 months of other conservative treatment modalities (injection, surgical, psychologic or physical), have been ineffective in relieving pain and improving function; and

(3) Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, physical examination and diagnostic testing); and

(4) Further surgical intervention or other treatment is not indicated or likely to be effective; and

(5) 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

(6) No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and

(7) There has been documented improvement in pain and function in response to oral opioid medications but intolerable adverse effects preclude their continued use; and

(8) 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.

(9) 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.

For most patients, it should be used as part of a program to facilitate restoration of function and return to activity, and not just for pain reduction. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical or other intervention is not indicated, there are no contraindications to a trial, psychological evaluation unequivocally states that the individual has realistic expectations and the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50% reduction in pain. (*Tutak, 1996*) (*Yoshida, 1996*) (*BlueCross BlueShield, 2005*) (*United Health Care, 2005*) See also Opioids and the Implantable drug-delivery systems (IDDSs). In a study of IDDS in 136 patients with low back pain, after one year 87% of the patients described their quality of life as fair to excellent, and 87% said they would repeat the implant procedure. However, complication rates (i.e., infection, dislodging, and cerebrospinal fluid leak) are likely to rise with time in these procedures and more longitudinal outcome studies need to be conducted. (*Deer, 2004*) In one survey involving 429 patients with nonmalignant pain treated with intrathecal therapy, physician reports of global pain relief scores were excellent in 52.4% of patients, good in 42.9%, and poor in 4.8%. In another study of 120 patients, the mean pain intensity score had fallen from 93.6 to 30.5 six months after initiation of therapy. In both studies, patients reported significant improvement in activities of daily living, quality of life measures, and satisfaction with the therapy. (*Winkelmuller, 1996*) (*Paice, 1997*) One study in patients suffering from chronic low back pain caused by failed back syndrome found a 27% improvement after 5 years for patients in the intrathecal drug therapy group, compared with a 12% improvement in the control group. (*Kumar, 2002*) Supporting empirical evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. Generally, use of implantable pumps is FDA approved and indicated for chronic intractable pain. Treatment conditions may include FBSS, CRPS, Arachnoiditis, Diffuse Cancer Pain, Osteoporosis, and Axial Somatic Pain. As we have gained more experience with this therapy, it has become apparent that even intrathecal opioids, when administered in the long term, can be associated with problems such as tolerance and other side effects. Consequently, long-term efficacy has not been convincingly proven. However, it is important to note that there is a distinction between "tolerance" and "addiction", and the levels of drugs administered intrathecally should be significantly below what might be needed orally in

their absence. (*Osenbach, 2001*) (*BlueCross BlueShield, 2005*) See also the section "Medications for IDDS if determined to be medically necessary" below.

Safety Precautions & Warnings: Oral opioid prescribing, use and how to best keep patients as safe as possible have all have been the subject of increasing discussion, in part, due to related accidental deaths. (*Phillips, 2008*) Use of intrathecal opioids, as for all routes of administration, is not without risk. Constipation, urinary retention, nausea, vomiting, and pruritus are typical early adverse effects of intrathecal morphine and are readily managed symptomatically. Other potential adverse effects include granuloma formation, amenorrhea, loss of libido, edema, respiratory depression, death, and pump and catheter malfunctions. (*Winkelmuller, 1996*) (*Paice, 1997*) (*Washington State Health Care Authority#2, 2008*) Common causes of mortality in implanted pump patients appear to be preventable through adherence to dosing and monitoring information for drugs approved for chronic intrathecal administration. Follow product instructions and dosing recommendations. Failure to comply with all implanted infusion pump product instructions can lead to technical errors or improper use and result in additional surgical procedures, a return of underlying symptoms, or a clinically significant drug underdose or fatal drug overdose. (*Medtronic, 2009*) The mortality rate in the implanted pump population is higher than some operative benchmarks and similar at approximately 30 days and 1-year post discharge to open spine surgery in the Medicare population. (*Coffey, 2009*) Patients who receive the implanted device should be monitored in an adequately equipped facility for a sufficient time to monitor drug effects. When using concomitant medications with respiratory or CNS depressant effects, appropriate supervision and monitoring should be provided. (*Medtronic, 2009*)

Patient selection (in addition to criteria below): *Cole 2003* recommends that, after other criteria are met, patients with neuropathic pain are better candidates for spinal cord stimulation (SCS), and patients with nociceptive pain are better candidates for intrathecal drug delivery (IDD). It also recommends psychological evaluation and clearance before any implantation, plus positive response to a trial. (*Cole, 2003*)

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*)

Claimant appealed the denial of the repeat intrathecal pump trial. Dr. EA with Medical Review Institute of America (MRIoA) opined that Claimant did not meet the ODG criteria for the repeat intrathecal pump trial. Dr. GA stated that there has been no prior intrathecal pump trial; however, Dr. EA noted that the medical records reflect that Claimant had an intrathecal pump trial on January 8, 2019. Dr. EA opined that the history and documentation do not support the request for a repeat intrathecal pump trial.

Claimant requested that an IRO be appointed to review the MRIoA denial. The Division appointed Specialty Independent Review Decision (SIRO) as the IRO. SIRO submitted the review of the request to a Board-Certified Anesthesiologist. In IRO Case No. 251933, the physician reviewer upheld the denial of the request for the repeat intrathecal pump trial. According to the physician reviewer, the ODG criteria for a trial of an intrathecal pump requires that non-opioid oral medication regimens have been tried and have failed to relieve pain and improve function and there has been documented improvement in pain and function in response to opioid medications, but intolerable adverse effects preclude their continued use. In this case, Claimant reports that he is taking Percocet and Lyrica which relieve his pain to a tolerable level and increases activities of daily living, without side effects. The physician review noted that Claimant appears to be tolerating oxycodone well and there is no indication that he has failed long acting morphine or long-acting oxycodone. The physician reviewer stated that Claimant does not meet the ODG criteria for an intrathecal pump trial; therefore, the request of a repeat intrathecal pump trial is not medically necessary.

Dr. GA argued that the recommendations of the ODG regarding the repeat intrathecal pump trial should not be allowed. According to Dr. GA, Claimant has ongoing pain and has not reached goal with the current treatment. According to Claimant there are activities that he cannot perform. There is, however, no persuasive expert medical evidence that would tend to show that the recommendations contained in the ODG do not apply to Claimant or that the treatment requested by Dr. GA is reasonably required for the compensable injury of (Date of Injury).

Based on a careful review of the evidence presented in the hearing, Claimant failed to meet his burden of overcoming the IRO decision. The IRO decision in this case is based on the ODG and the evidence revealed that Claimant failed to meet all the necessary criteria for a repeat intrathecal pump trial. The preponderance of the evidence-based medicine is not contrary to the decision of the IRO and, consequently, Claimant is not entitled to the repeat intrathecal pump trial.

The Administrative Law Judge 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. The Texas Department of Insurance, Division of Workers Compensation has jurisdiction over 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 Liberty Insurance Corporation, Carrier.

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 Administrative Law Judge's Exhibit Number 2.

3. Complex regional pain syndrome is a component of the compensable injury.

4. The repeat intrathecal pump is not health care reasonably required for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Workers' Compensation Division of the Texas Department of Insurance 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 Independent Review Organization that a repeat intrathecal pump trial is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

The preponderance of the evidence is not contrary to the decision of the Independent Review Organization that a repeat intrathecal pump trial is not health care reasonably required 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 **LIBERTY INSURANCE CORPORATION, CARRIER**, and the name and address of its registered agent for service of process is

CORPORATION SERVICE COMPANY
211 E 7th STREET, SUITE 620
AUSTIN, TEXAS 78701

Signed this 13th day of August, 2019

Early Moye
Administrative Law Judge