

MEDICAL CONTESTED CASE HEARING NO. 15055

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and the Rules of the Division of Workers' Compensation. For the reasons discussed herein, the Hearing Officer determines that Claimant is not entitled to an outpatient (OP) intrathecal pain pump trial for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

A contested case hearing (CCH) was held on August 18, 2015 to decide the following disputed issue:

Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Claimant is not entitled to the OP intrathecal pain pump trial for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and represented himself. He signed an ombudsman waiver request at the hearing and elected to waive the assistance of an ombudsman, however, TL, remained in the room. Respondent/Carrier appeared and was represented by BJ, an attorney.

DISCUSSION

The evidence presented in the hearing reveals that on (Date of Injury), Claimant slipped and fell injuring his left upper extremity. Subsequently, he was diagnosed with a shoulder strain, hand sprain, cervical herniated nucleus pulposus, casusalgia of the upper extremity, chronic pain syndrome and cervical radiculopathy. Claimant's course of treatment has included physical therapy, injections, TENS unit, and several different types of oral medications. On February 26, 2013, Claimant underwent left shoulder surgery and biceps open tenodesis and three months later, Dr. DK performed a supraclavicular exploration of the left brachial plexus and external neurolysis of C5 and C6. The evidence indicates an upper extremity EMG/NCS dated June 2014 revealed persistent brachial plexopathy.

The evidence further reflects that Claimant continued to complain of severe pain in his left upper extremity and he began treatment by taking oral Methadone. A progress note dated February 24, 2015 indicates Claimant rated his pain at 7-9 out of 10, and that Methadone seemed to be helping in lowering dosing. Claimant testified that he could not handle taking oral Methodone because it made him hallucinate and caused other severe side effects including cardiac problems. His treating doctor, Dr. AT, MD, submitted a request for the proposed OP intrathecal pain pump trial

and it was denied by two Utilization Review Agents (URAs) – one on an initial review, the other following a request for reconsideration. After the adverse determination by the URA, Claimant appealed to an Independent Review Organization (IRO). The IRO reviewer, board certified in anesthesiology, upheld the URA denial of the proposed treatment.

The IRO reviewer determined that the requested OP intrathecal pain pump trial was not health care reasonably required for Claimant's compensable injury of (Date of Injury). As part of the IRO report, on April 20, 2015, the IRO reviewer noted that guidelines indicate that for the use of this type of treatment, non-opiate oral medications regimens should have been tried and it should be documented that they failed to relieve pain and improve function. Also, there should be documented improvement in pain and function in response to oral opiate medications, but that intolerable adverse effects precluded their continued use. However, the IRO reviewer explained that records provided for review indicate that Claimant was achieving appropriate analgesia with Methadone in lowering dosing, without significant side effects. Claimant appealed the IRO decision and requested this medical CCH to determine the medical necessity of the proposed OP intrathecal pain pump trial.

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 the preponderance of evidence-based medical evidence."

Petitioner/Claimant, as the parties challenging the IRO decision, has the burden of proof to overcome that decision by the preponderance of evidence-based medical evidence. Evidence-based medical evidence entails the opinion of a qualified expert that has some basis in evidence-based medicine. Expert evidence is required in all medical necessity disputes and Claimant's lay testimony is not probative on questions requiring expert evidence, such as the inquiry into the medical necessity of the procedure at issue.

The ODG Pain Chapter provides as follows in the entry related to Implantable Delivery Drug Systems (IDDS) –

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. There is insufficient evidence to recommend the use of implantable drug-delivery systems (IDDS) for the treatment of chronic pain. There are no high quality studies on this topic that document that this therapy is safe and effective. Further, significant complications and adverse events have been documented and the data identifies a substantial risk to patients. (Washington State Health Care Authority, 2008) Results of studies of opioids for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of opioids for severe cases, not to exceed 2 weeks, and do not support chronic use (for which a pump would be used). This treatment may be considered relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) (Deer, 2009) (Patel, 2009) 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, 2005) (United Health Care, 2005) See also Opioids and the Low Back Chapter. 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 Intrathecal drug delivery systems, medications.

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)

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.

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 testified at the hearing in support of the medical necessity of the proposed OP intrathecal pain pump trial treatment for the relief of his chronic pain that is interfering with his life. He stated that he suffers from severe nerve damage and that he has no mobility in his left arm, stemming from his left shoulder surgery. He explained that his treating doctor is not willing to get involved in this matter and would not write a letter or testify at the hearing explaining how the proposed health care is medically necessary. Claimant's testimony was found to be credible and consistent with regard to his persistent brachial plexopathy and continued symptoms of chronic pain following the compensable injury of (Date of Injury); however, no expert medical evidence was submitted to overcome the decision of the IRO by the preponderance of the evidence-based medical evidence.

Carrier presented the testimony of BJ B, M.D., board-certified in physical medicine and rehabilitation, at the hearing. Dr. B stated that he agreed with the IRO decision. He testified that

an intrathecal pain pump is the temporary placement under the skin of a drug-delivery system that holds pain medication with a catheter. He stated that the requested health care fails to meet ODG recommended treatment because Claimant has not tried other pain medications that have been shown to be useful and successful for the treatment of chronic pain and that the requested intrathecal pain pump was recommended by his treating doctor without exhausting other conservative, less invasive methods of treatment. Dr. B described Claimant's treatment involving Methadone and testified that the medical records reflect that Claimant was initially given a high dose of Methadone, but later was receiving some pain relief with Methadone in lower doses.

Based on the evidence presented, Petitioner/Claimant did not meet his burden of proof to overcome the decision of the IRO by the preponderance of evidence-based medical evidence. As the preponderance of the evidence is not contrary to the decision of the IRO that the requested OP intrathecal pain pump trial is not health care reasonably required for the compensable injury of (Date of Injury), Claimant is held not to be entitled to that procedure.

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 and sustained a compensable injury.
 - C. On (Date of Injury), Employer provided workers' compensation insurance coverage with Texas Mutual Insurance Company, Carrier.
 - D. The Independent Review Organization (IRO) determined that the health care at issue is not reasonably required 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. The OP intrathecal pain pump trial 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 Independent Review Organization (IRO) that the OP intrathecal pain pump trial is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to the OP intrathecal pain pump trial 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 **TEXAS MUTUAL INSURANCE COMPANY**, and the name and address of its registered agent for service of process is

**MR. RICHARD GERGASKO, PRESIDENT
6210 EAST HIGHWAY 290
AUSTIN, TEXAS 78723**

Signed this 20th day of August, 2015.

Marilyn J. Allen
Hearing Officer