MEDICAL CONTESTED CASE HEARING NO. 13050

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.

ISSUE

A medical contested case hearing was held on January 17, 2013, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (hereinafter "IRO") that Claimant is not entitled to morphine pump refill for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner appeared without representation. Claimant appeared and was assisted by IF, ombudsman. Respondent appeared and was represented by CA, attorney.

EVIDENCE PRESENTED

The following witnesses testified:

For Petitioner: Petitioner.

For Claimant: Claimant.

For Respondent: None.

The following exhibits were admitted into evidence:

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

Petitioner's Exhibit P-1.

Claimant's Exhibits C-1 through C-10.

Respondent's Exhibits R-A through R-E.

BACKGROUND INFORMATION

Claimant was a carpenter for the employer, (Employer). On (Date of Injury), while assembling a metal structure, his left foot became caught in the steel rods and was fractured. Claimant has seen several health care providers throughout the course of medical treatment for his injury. The compensable injury of (Date of Injury) was determined to include or extend to include reflex sympathetic dystrophy (RSD) or complex regional pain syndrome (CRPS) to the left lower extremity, depression and anxiety. There was no dispute that this was a compensable injury. Claimant received medical treatment for his injuries and had an intrathecal pump (i.e., morphine pump) implanted on January 18, 2008. The intrathecal pump was removed on February 24, 2008 due to infection. A replacement intrathecal pump was implanted on October 2, 2008 and Claimant continued with medical treatment being seen by several health care providers. Eventually, Petitioner, who is board certified in anesthesiology and pain medicine, saw him. Petitioner requested a morphine pump refill. Such requested treatment underwent utilization review and was denied on June 13, 2012 by CS, M.D. Reconsideration was requested and such reconsideration was denied on July 17, 2012 by PL, M.D. Petitioner then appealed the denials to an IRO and the IRO reviewer upheld the previous adverse determinations. Consequently, Petitioner appealed the IRO decision and this is the reason for the present discussion and decision.

DISCUSSION

Medical Necessity

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. TEX. LAB. CODE § 408.021. "Health care reasonably required" is defined 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. TEX. LAB. CODE § 401.011 (22a). Health care under the Texas Workers' Compensation system must be consistent with evidence-based medicine if that evidence is available. "Evidence-based medicine" means 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. TEX. LAB. CODE § 401.011 (18a). 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. TEX. LAB. CODE § 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with the Texas Labor Code. TEX. LAB. CODE § 413.017(1).

In accordance with the above statutory guidance, the Division has adopted treatment guidelines by rule. 28 Tex. Admin. Code § 137.100 (Division Rule 137.100). This Rule directs health care providers to provide treatment in accordance with the current edition of the *Official Disability Guidelines* (hereinafter "ODG") and that 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.

The pertinent provisions of the ODG applicable to this case are as follows, to wit:

> **Implantable drug-delivery systems (IDDSs):**
>
> Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial. 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), although IDDSs may be appropriate in selected cases of chronic, severe low back pain or failed back syndrome. This treatment should only be used 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 BlueShield, 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 opiates, when administered in the long term, can be associated with problems such as tolerance, hyperalgesia, 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. (Osenback, 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 amenorrhea, loss of libido, edema, respiratory depression, accidental death and technical issues with the intrathecal system. (Winkelmuller, 1996) (Paice, 1997) 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) Monitor patients in an adequately equipped

facility for a sufficient time to monitor drug effects. When using concomitant medications with respiratory or CNS depressant effects, provide appropriate supervision and monitoring. (Medtronic, 2009)

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)

Patient selection (in addition to criteria below): This textbook 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 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 opiates or non-opiate 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) opiates 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:
  1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, injection, surgical, psychologic or physical), if appropriate and not contraindicated; and
  2. Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, exam and diagnostic testing); and
  3. Further surgical intervention or other treatment is not indicated or likely to be effective; and
  4. 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
  5. No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and
  6. 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 1-5 above are met.

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

Intrathecal drug delivery systems, medications:

Recommended as indicated below.
Recommended 1st 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) It can be seen that there has been a substantial decrease in concentration (particularly for hydromorphone). The newer maximum concentrations were recommended, in part, to prevent granulomas.
Recommended 2nd 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)
Recommended 3rd 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). The 2007 Polyanalgesic Consensus Conference Recommendations for the Management of Pain by Intrathecal Drug Delivery concluded that ziconotide should be updated to a first-line intrathecal drug. This recommendation was published in a journal not yet accepted for inclusion in MEDLINE and the conference was sponsored by Elan Pharmaceuticals. (Deer, 2007)

CRPS, treatment:

Recommended hierarchy of options as indicated below. The goal is to improve function. Multiple pathophysiological mechanisms are responsible including neuropathic (sympathetic and independently-maintained pain), and immunologic

(regional inflammation and altered human leukocyte antigens). Both peripheral sensitization and central sensitization have been proposed. (Ribbers, 2003) (Stanton-Hicks, 2006) There are no evidence-based treatment guidelines but several groups have begun to organize treatment algorithms. Recommendations:

1. *Rehabilitation:*
   (a) *Early stages:* Build a therapeutic alliance. Analgesia, encouragement and education are key. Physical modalities include desensitization, isometric exercises, resisted range of motion, and stress loading. If not applied appropriately, PT can actually be detrimental.
   (b) *Next steps:* Increase flexibility with introduction of gentle active ROM and stretching (to treat accompanying myofascial pain syndrome). Other modalities may include muscle relaxants, trigger point injections and electrical stimulation (based on anecdotal evidence). Edema control may also be required (elevation, retrograde sympathetic blocks, diuretics and adrenoceptor blockers when sympathetically maintained pain-SMP is present).
   (c) *Continued steps:* Continue active ROM; stress loading; scrubbing techniques; isotonic strengthening; general aerobic conditioning; and postural normalization.
   (d) *Final steps:* Normalization of use; assessment of ergonomics, posture and modifications at home and work. In some cases increased requirements of analgesic medications, psychotherapy, invasive anesthetic techniques and SCS may be required. See CRPS, spinal cord stimulators.
2. *Psychological treatment:* Focused on improved quality of life, development of pain coping skills, cognitive-behavioral therapy, and improving facilitation of other modalities.
   (a) Early stages: education.
   (b) Next steps: clinical psychological assessment (after 6 to 8 weeks): identification of stressors; identification of comorbid Axis I psychiatric disorders (depression, anxiety, panic and post-traumatic stress).
3. *Pain management:*
   (c) *Pharmacological:* antidepressants (particularly amitriptyline); anticonvulsants (particularly gabapentin); steroids; NSAIDS; opioids; calcitonin; bisphosphonates; α1 adrenoceptor antagonists (terazosin or phenoxybenzamine). The latter class of drugs has been helpful in SMP. Clonidine has been given transdermally and epidurally. (See CRPS, medications.) Bisphosphonates have some literature support in the presence of osteopenia. (Rho, 2002)

(d) *Minimally invasive*: depends on degree of SMP, stage of rehabilitation (passive or active movement), and response to blocks. (See CRPS, sympathetic blocks.) Responders to sympathetic blocks (3 to 6 blocks with concomitant PT) may be all that is required. For non-responders somatic block or epidural infusion may be required to optimize analgesia for PT.

(e) *More invasive:* After failure of progression or partial relief, consider tunneled epidural catheters for prolonged sympathetic or somatic blocks or neurostimulation with SCS in CRPS-I and II. See CRPS, spinal cord stimulators. Also consider peripheral nerve stimulation in CRPS-II and intrathecal drug delivery in patients with dystonia, failed neurostimulation, long-standing disease, multi-limb involvement and requirement of palliative care.

(f) *Surgical:* Sympathectomy is not generally recommended, but has been considered in patients that respond to sympathetic blocks. Pre-procedure the patient should have outcomes assessed with radiofrequency and neurolytic procedures. (See CRPS, sympathectomy.) Motor Cortex Stimulation has been considered.

Outcome measures for all treatments of CRPS: Objective measures such as the the Beck Depression Inventory, the State Trait Anxiety Inventory, McGill Pain Questionnaire-Short Form, the Pain Disability Index, & the Treatment Outcomes in Pain Survey (the last three may not meet the APA standards for standardized test in clinical use). See Psychological evaluations. See also CRPS, diagnostic criteria; CRPS, medications; CRPS, prevention; CRPS, sympathetic blocks; & Sympathetically maintained pain (SMP). See also Spinal cord stimulators (SCS).

In the instant case, the utilization review doctors denied the requested treatment and the IRO reviewer upheld the denial of the requested treatment. The IRO reviewer who is board certified in anesthesiology and pain management reviewed Petitioner's records and opined that the proposed procedure was not indicated as medically necessary based on the clinical data provided. Thereafter, the IRO reviewer cited medical judgment, clinical experience and expertise in accordance with accepted medical standards and the ODG in upholding the denials of the requested treatment.

When weighing expert testimony, the hearing officer must first determine whether the doctor rendering an expert opinion is qualified to offer such. In addition, the hearing officer must determine whether the opinion is relevant to the issues at bar and whether it is based upon a reliable foundation. An expert's bald assurance of validity is not enough. *See Black v. Food Lion, Inc.*, 171 F.3d 308 (5th Cir. 1999); *E.I. Du Pont De Nemours and Company, Inc. v.*

Robinson, 923 S.W.2d 549 (Tex. 1995). A medical doctor is not automatically qualified as an expert on every medical question and an unsupported opinion has little, if any, weight. *See Black*, 171 F.3d 308. In determining reliability of the evidence, the hearing officer must consider the evidence in terms of

(1) general acceptance of the theory and technique by the relevant scientific community;
(2) the expert's qualifications;
(3) the existence of literature supporting or rejecting the theory;
(4) the technique's potential rate of error;
(5) the availability of other experts to test and evaluate the technique;
(6) the clarity with which the theory or technique can be explained to the trial court; and the experience and skill of the person who applied the technique on the occasion in question

Kelly v. State, 792 S.W.2d 579 (Tex. App.-Fort Worth 1990) *aff'd*, 824 S.W.2d 568 (Tex. Crim. App. 1992).

Additionally, "[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." *See* Division Rule 133.308 (t). "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." *Id.*

Accordingly, Petitioner, as the party appealing the IRO decision, had the burden of overcoming the IRO decision by a preponderance of evidence-based medical evidence. In this case, Petitioner presented testimonial and documentary evidence. It was evident that Claimant had reflex sympathetic dystrophy (RSD) or complex regional pain syndrome (CRPS) to the left lower extremity, depression, and anxiety and an intrathecal pump (i.e., morphine pump) in his body that was empty. There was evidence presented that the IRO reviewer may not have had and/or may not have reviewed all of Claimant's medical records. Furthermore, it did not appear from a review of the ODG, that an intrathecal pump refill is specifically addressed as recommended or not. Petitioner presented his own testimony in that an intrathecal pump refill is medically reasonable and necessary, otherwise there would be no need for the intrathecal pump. He further stated that he did not know of evidence-based medicine that existed for this scenario and that generally accepted standards of medical practice recognized in the medical community would allow for the proposed intrathecal pump refill. As such, there was sufficient medical explanation that the requested treatment was medically reasonable and necessary. Therefore, the preponderance of the evidence is contrary to the decision of the IRO that Claimant is not entitled to morphine pump refill for the compensable injury of (Date of 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), the Employer.

   C. On (Date of Injury), Employer provided workers' compensation with Zurich American Insurance Company.

   D. On (Date of Injury), Claimant sustained a compensable injury.

2. Respondent / Carrier delivered to Petitioner and Claimant a single document stating the true corporate name of Respondent / Carrier, and the name and street address of Respondent / Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. The IRO determined that Claimant is not entitled to morphine pump refill for the compensable injury of (Date of Injury).

4. Morphine pump refill is 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 contrary to the decision of the IRO that Claimant is not entitled to morphine pump refill for the compensable injury of (Date of Injury).

DECISION

Claimant is entitled to morphine pump refill for the compensable injury of (Date of Injury).

ORDER

Carrier is ordered to pay benefits in accordance with this decision, the Texas Workers' Compensation Act, and the Commissioner's Rules.

The true corporate name of the insurance carrier is **ZURICH AMERICAN INSURANCE COMPANY** and the name and address of its registered agent for service of process is

ZURICH AMERICAN INSURANCE COMPANY
CORPORATION SERVICE COMPANY
211 EAST 7TH STREET, SUITE 620
AUSTIN, TX 78701-3232

Signed this 25th day of January 2013.

Julio Gomez, Jr.
Hearing Officer