MEDICAL CONTESTED CASE HEARING NO. 09175
M6-09-14457-01

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 contested case hearing was opened on February 19, 2009 with the record closing on May 19, 2009 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 outpatient placement of lumbar permanent intrathecal pump for the compensable injury of _____?

PARTIES PRESENT

Claimant appeared and was assisted by DB, ombudsman. Carrier appeared and was represented by GS, attorney.

BACKGROUND INFORMATION

It was undisputed that Claimant sustained a compensable neck and low back injury on _____. Prior to beginning treatment on September 13, 2006 with Dr. C, who is board certified in anesthesiology and pain medicine, the Claimant, who is 67 years old, had undergone extensive lumbar spine surgery with instrumentation for the _____ injury. After beginning treatment with Dr. C, the Claimant continued to suffer from low back pain, pain radiating into the lower extremities, neck pain and headaches. Dr. C noted that after more than six months of oral medications, including NSAIDS, AED's, narcotic/non-narcotic analgesics, and anti-depressants, as well as several spinal injections with steroids, the Claimant's symptoms did not improve. He referred her to a spine surgeon, Dr. K, who determined that she was not a surgical candidate. He thereafter prepared her for an intrathecal narcotic trial by discontinuing her use of long-acting narcotics and maintaining her on Darvocet. Dr. C testified that on April 11, 2008, the Claimant underwent a trial of intrathecal narcotics, which reduced her pain level by 70%. He testified that prior to the trial, the Claimant's level of lumbar pain on a VAS scale was 5/10, and her cervical VAS was 8/10, but in the interval immediately following the trial her lumbar VAS was 0/10 and her cervical VAS was 5/10. After the trial, the Claimant was discharged home and reported a 60% increase in her functional capability for the following 24 hours, according to Dr. C's testimony. He thereafter recommended the outpatient placement of an intrathecal narcotic pump, which was denied by the Carrier. The Claimant requested that an IRO be appointed to review the Carrier's denials and the IRO physician reviewer, who is board certified in pain management and anesthesiology, upheld the Carrier's denials. The Claimant then requested this contested case hearing to appeal the IRO decision.

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. Section 401.011(22-a) defines health care reasonably required 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: (A) evidence based medicine; or (B) if that evidence is not available, generally accepted standards of medical practice recognized in the medical community."

"Evidence based medicine" is further defined, by Section 401.011(18-a) as 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 Division of Workers' Compensation has adopted treatment guidelines under Division Rule 137.100. That rule requires that health care providers provide treatment in accordance with the current edition of the *Official Disability Guidelines (*ODG*),* and treatment provided pursuant to those guidelines is presumed to be health care reasonably required as mandated by the above-referenced sections of the Texas Labor Code.

The initial inquiry in any dispute regarding medical necessity, is whether the proposed care is consistent with the ODG. The ODG discusses implantable drug-delivery systems (IDDSs) as follows:

> **Implantable drug-delivery systems (IDDSs)**
> Recommended only as an end-stage treatment alternative in selected cases of chronic intractable pain. See the Pain Chapter for *Indications for Implantable drug-delivery systems (IDDSs)*. 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. 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 intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50-70% reduction in pain. See the Pain Chapter for references.
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> **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) 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. 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, and technical issues with the intrathecal system. (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. (Osenbach, 2001) (BlueCross BlueShield, 2005) See also Intrathecal drug delivery systems, medications

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)

Indications for Implantable drug-delivery systems:

Implantable infusion pumps are considered medically necessary when used to deliver drugs for the treatment of:

- o Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents);
- o Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents);
- o Head/neck cancers (intra-arterial injection of chemotherapeutic agents);
- o 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. 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. 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. 3. Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and
4. 4. No contraindications to implantation exist such as sepsis or coagulopathy; and
5. 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.

As noted previously herein, "health care reasonably required" means 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 that evidence is not available, generally accepted standards of medical practice recognized in the medical community. Treatment provided pursuant to the ODG is presumed to be health care reasonably required.

The Carrier's utilization reviewers and the pain management IRO reviewer denied the requested procedure citing the relevant provisions of the ODG. Specifically, the IRO noted the fact that the ODG considers that a "temporary trial of spinal (epidural or intrathecal) opiates is considered successful if the patient receives at least 50-70% reduction in pain and there is documentation in the medical record of functional improvement and associated reduction in oral pain medication use." The IRO reviewer noted that in this case, none of this information was mentioned in the

documentation that was provided to the IRO reviewer. The IRO reviewer also noted that it is difficult to tell whether the trial was successful since the Claimant received epidural Marcaine during the trial, in addition to intrathecal Morphine. For these reasons, the IRO reviewer concluded that medical necessity of the requested procedure had not been demonstrated.

Dr. C testified that he is familiar with the ODG, and that this treatment is recommended given the Claimant's circumstances. He testified that he did document the Claimant's reduction in pain and improvement in function due to the trial, and that she meets the requirements of the ODG for implantation of an intrathecal pump.

Dr. N, a board certified anesthesiologist, also testified, and she stated that she participated in writing certain portions of the ODG regarding pain medications/programs. She also testified that she did multiple pre-authorizations in this case for the Carrier, and she has spoken by telephone to Dr. C about the Claimant and the placement of the intrathecal pump. Dr. N testified that she did not recommend approval of the pump for several reasons, including that while a psychological evaluation was performed upon the Claimant, it does not meet the requirements as set forth in the ODG; the Claimant has depression, which is a contraindication for the pump; regarding the Claimant's neck pain, a large quantity or dosage of the medication would be required for pain relief in that area, since the pump would be implanted in her lumbar area; Claimant will still need oral pain medications for effective pain relief; the side effects of the pump are that it can accelerate menopause and affect osteoporosis; and there are complications in connection with the implantation of the pump, including possible problems with the catheter staying in place.

When both parties cite the ODG in support of their position, that position must be supported by sufficient evidence to justify application of the ODG. Mere citation to the ODG does not carry the day. When weighing medical evidence, the hearing officer must first determine whether the doctor giving the expert opinion is qualified to offer it, but also, the hearing officer must determine whether the opinion is relevant to the issues in the case and whether the opinion is based upon a reliable foundation. An expert's bald assurance of validity is not enough. *See* ***Black v. Food Lion, Inc.***, 171 F.3rd 308 (5th Cir. 1999); ***E.I. Du Pont De Nemours and Company, Inc. v. Robinson***, 923 S.W.2d 549 (Tex. 1995). When determining reliability, 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 (7) 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).

While the Claimant's testimony about her symptoms was credible, she failed to present an evidence-based medical opinion from a competent source to overcome the IRO's decision. The treatment proposed by Dr. C is recommended by the ODG when all the requirements are met for the treatment of non-malignant pain, but in this case the evidence does not establish that all the requirements have been met. As a pain management specialist, Dr. C is certainly qualified to render an opinion regarding the treatment of chronic lumbar and cervical pain. His testimony in this case regarding Claimant's satisfaction of the ODG criteria, however, was not sufficient to overcome the IRO.

The preponderance of the evidence is not contrary to the IRO decision and the requested outpatient placement of a lumbar permanent intrathecal pump does not meet the criteria set out in the ODG.

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

   B. On _____, Claimant was the employee of the (Employer).

   C. On _____, Claimant sustained a compensable neck and low back injury while in the course and scope of her employment with the (Employer).

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

3. Claimant's doctor recommended the outpatient placement of a lumbar permanent intrathecal pump for the treatment of Claimant's compensable _____ injury.

4. The IRO determined that the requested outpatient placement of a lumbar permanent intrathecal pump is inconsistent with the treatment guidelines set forth in the ODG and that the Carrier's denial of the procedure should be upheld.

5. The requested outpatient placement of a lumbar permanent intrathecal pump is not health care reasonably required for the compensable injury of _____.

CONCLUSIONS OF LAW

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

2. Venue was proper in the (City) Field Office.

3. The preponderance of the evidence is not contrary to the decision of IRO that the outpatient placement of a lumbar permanent intrathecal pump is not healthcare reasonably required for the compensable injury of _____.

DECISION

Claimant is not entitled to an outpatient placement of a lumbar permanent intrathecal pump for the compensable injury of _____.

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.

The true corporate name of the self-insured carrier is **(EMPLOYER)** and the name and address of its registered agent for service of process is

HONORABLE MAYOR LS
(ADDRESS)
(CITY), TX (ZIP CODE)

Signed this 29th day of May, 2009.

Patrice Fleming-Squirewell
Hearing Officer