MEDICAL CONTESTED CASE HEARING NO. 09034

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 benefit contested case hearing was held on October 7, 2008, to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IR0) that Claimant is not entitled to Clonazepam (1mg 1-2 a day), Methadone (10 mg - 2 in the morning and 1 midday), and Cyclobenzaprine (10 mg – 1 pill 3x prn) for the compensable injury of _____?

PARTIES PRESENT

Claimant appeared and was assisted by ombudsman, JT. Carrier appeared and was represented by attorney, TW.

BACKGROUND INFORMATION

It is undisputed that Claimant sustained an injury to his low back during the course and scope of his employment on _____. Claimant underwent an L5-S1 fusion on June 6, 2007. He testified that he continues to have pain in his low back, which radiates down his leg and causes his foot to drop occasionally.

Claimant currently treats with a pain management doctor, Dr. H, and a neurosurgeon, Dr. LG. Dr. LG, the neurosurgeon who performed Claimant's fusion surgery in June of 2007, followed Claimant's postoperative progress and noted diminished low back mobility as well as low back, hip and leg pain. He also noted a progressive fusion with stable position.

A postsurgical MRI revealed the hardware, 4 to 5 MM anterolisthesis of L5 on S1, and extradural fluid collections in the surgical region; but, revealed no stenosis or nerve root encroachment at the surgical area or any other level.

Follow-up x-rays showed stable post-operative changes and no hardware complications as late as January 3, 2008.

Dr. H, the pain management doctor, has diagnosed failed back surgery syndrome and prescribed Methadone, Clonazepam and Cyclobenzaprine for treatment of the compensable injury on March 10, 2008.

The carrier denied these medications. The first utilization review doctor, Dr. S, a DO in

occupational and preventive medicine, cited the *Official Disability Guidelines* Low Back and Pain Chapters and denied the requested medications.

The utilization review doctor who reviewed the request on reconsideration, Dr. B, a DO in anesthesiology, a neurosurgeon, also denied the requested medications. He also cited the *ODG* indications for the requested medications and refused to certify those medications. The doctor explained that the records did not support the effectiveness of Methadone and there was no quantitative assessment on how they help, no expression of the percentage of relief, no mention of how long the relief lasts, no mention of urine tox screens to show compliance, and no mention of increase in function or activity. He further explained that, due to the danger of addiction and withdrawal from Methadone per the *ODG*, there needs to be documentation of the effectiveness of all pain medications. He stated that per the *ODG* Benzodiazepines like Clonazepam are not recommended for long-term use (most guidelines limit use to 4 weeks) because long term efficacy is unproven and there is a risk of dependence. Finally, he opined that the records did not support the effectiveness of Cyclobenzaprine, as there was no quantitative assessment of how they help, no mention of the percentage of relief, no mention of how long the effects last; and, it is usually used in short courses, not as a chronic medication. Based on the clinical information submitted and using the referenced sections of the *ODG*, the doctor denied the requested medications.

An IRO reviewer and board certified anesthesiologist specializing in pain management reviewed the records and upheld the adverse determinations of the utilization review doctors. The IRO denied the medications citing the *ODG*. The IRO doctor noted that the *ODG* states that opiates (Methadone) are reasonable and necessary if there is documented improvement in comfort and function; that Clonazepam may be effective for back pain if there is documentation of efficacy; and, Cyclobenzaprine is questionable for chronic pain, but may be effective with documented improvement in function and increased activity. Because the records reviewed lacked documentation regarding efficacy and improvement, the IRO doctor found that the requested medications were not reasonable and necessary.

DISCUSSION

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**.

ODG

The initial inquiry, therefore, in any dispute regarding medical necessity, is whether the proposed care is consistent with the *ODG*. As the utilization review and IRO doctors in the instant case have stated, the *ODG* allows for the use of all of the medications requested, with specific limitations and requires documentation of improved function and activity as well as efficacy in pain control for use of the medications.

The *ODG* Treatment Guidelines for chronic pain medications discuss the requested medications as follows:

Medications for subacute and chronic pain Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices listed separately (not all recomended). See Anticonvulsants for chronic pain; Antidepressants for chronic pain; Antidepressants for neuropathic pain; Antidepressants for non-neuropathic pain; Anxiety medications in chronic pain; Anti-epilepsy drugs (AEDs); Anti-Inflammatories; Benzodiazepines; Boswellia Serrata Resin (Frankincense); Buprenorphine; Cannabinoids; Capsaicin; Cod liver oil; Curcumin (Turmeric); Cyclobenzaprine (Flexeril®); Duloxetine (Cymbalta®); Gabapentin (Neurontin®); Glucosamine (and Chondroitin Sulfate); Green tea; Herbal medicines; Implantable drug-delivery systems (IDDSs); Injection with anaesthetics and/or steroids; Insomnia treatment; Intrathecal drug delivery systems, medications; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Ketamine; Methadone; Milnacipran (Ixel®); Muscle relaxants; Nonprescription medications; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; Opioids (with links to multiple topics on opioids); Pycnogenol (maritime pine bark); Salicylate topicals; Topical analgesics; Uncaria Tomentosa (Cat's Claw); Venlafaxine (Effexor®); White willow bark; & Ziconotide (Prialt®).

Benzodiazepines (Clonazepam) Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an

antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) See also Anxiety medications in chronic pain; & Insomnia treatment.

Methadone Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours.
Pharmcokinetics: Genetic differences appear to influence how an individual will respond to this medication. Following oral administration, significantly different blood concentrations may be obtained. Vigilance is suggested in treatment initiation, conversion from another opioid to methadone, and when titrating the methadone dose. (Weschules 2008) (Fredheim 2008)
Adverse effects: Delayed adverse effects may occur due to methadone accumulation during chronic administration. Systemic toxicity is more likely to occur in patients previously exposed to high doses of opioids. This may be related to tolerance that develops related to the N-methyl-D-aspartate (NMDA) receptor antagonist. Patients may respond to lower doses of methadone than would be expected based on this antagonism. One severe side effect is respiratory depression (which persists longer than the analgesic effect). Methadone should be given with caution to patients with decreased respiratory reserve (asthma, COPD, sleep apnea, severe obesity). QT prolongation with resultant serious arrhythmia has also been noted. Use methadone carefully in patients with cardiac hypertrophy and in patients at risk for hypokalemia (including those patients on diuretics). Methadone does have the potential for abuse. Precautions are necessary as well for employees in safety sensitive positions, including operation of a motor vehicle.
The ODG sets out specific steps for prescribing Methadone, all of which are set out at length in the first utilization review doctor's report.

Cyclobenzaprine Recommended as an option, using a short course of therapy. See Medications for subacute & chronic pain for other preferred options. Cyclobenzaprine (Flexeril®) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. (Kinkade, 2007) Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by Ortho McNeil Pharmaceutical.

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.

Both of the utilization review doctors and the IRO doctor denied the requested medications citing

the relevant provisions of the *ODG*, specifically the necessity for documentation of improvement with and efficacy of the medications and relatively short courses of some of the medications. It is incumbent on the Claimant, therefore, to provide evidence-based medicine sufficient to overcome the presumption afforded the *ODG* and the opinions of the doctors correctly applying the *ODG*.

Other Evidence Based Medicine

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).

Claimant failed to present an evidence-based medical opinion from a competent source to overcome the IRO's decision. The medications prescribed by Dr. H departed from the *ODG* in several respects, specifically in the lack of documentation of their effectiveness in controlling Claimant's pain and improving his function and activity. Further, the reports of Dr. H do not provide the necessary documentation to support the use of the prescribed medications for Claimant's compensable injury. Dr. H was asked very specifically, by the ombudsman, to offer an evidence-based medicine opinion regarding the requested medications. His records, without sufficient reference to the *ODG* or other evidence-based medicine justifying departure from the *ODG*, do not meet the requisite evidentiary standard required to overcome the presumption afforded the IRO. The preponderance of the evidence is not contrary to the IRO decision and the requested medications do 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 is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

   B. On _____, Claimant was the employee of (Employer), when he sustained a compensable injury.

   C. The IRO determined that the requested medications were not reasonable and necessary health care services for the compensable injury of _____.

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 treating pain management doctor prescribed Clonazepam (1mg 1-2 a day), Methadone (10 mg - 2 in the morning and 1 midday), and Cyclobenzaprine (10 mg – 1 pill 3x prn) for the compensable injury of _____.

4. The *ODG* allows for the use of all of the medications requested, with specific limitations and requires documentation of improved function and activity as well as efficacy in pain control for use of the medications..

5. The IRO decision upheld the Carrier's denial of the requested medications because the requesting doctor's records lacked documentation regarding efficacy and improvement with the use of the medications.

6. The requested medications are not consistent with the *ODG* criteria for medications for subacute and chronic pain.

7. The requested prescriptions are 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 IR0 that the medications Clonazepam (1mg 1-2 a day), Methadone (10 mg - 2 in the morning and 1 midday), and Cyclobenzaprine (10 mg – 1 pill 3x prn) are not health care reasonably required for the compensable injury of _____.

DECISION

Claimant is not entitled to Clonazepam (1mg 1-2 a day), Methadone (10 mg - 2 in the morning and 1 midday), and Cyclobenzaprine (10 mg – 1 pill 3x prn) 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 insurance carrier is **AMERICAN CASUALTY COMPANY OF READING, PENNSYLVANIA** and the name and address of its registered agent for service of process is

CT CORPORATION SYSTEM
350 NORTH ST. PAUL STREET
DALLAS, TEXAS 75201

Signed this 7th day of October, 2008.

Erika Copeland
Hearing Officer