MEDICAL CONTESTED CASE HEARING NO. 11046
M6-10-28382-01

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.

ISSUES

A contested case hearing was held on October 6, 2010, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that Claimant is entitled to Baclofen 10 mg 1 po TID #90 for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Carrier appeared and was represented by attorney JC. Dr. M M.D., Health Care Provider/Respondent appeared by telephone and Claimant appeared in person, and both were represented by attorney JD.

BACKGROUND INFORMATION

Claimant sustained a left foot and ankle injury while employed at (Employer) on _____. Claimant's compensable injury includes complex regional pain syndrome (CRPS). Claimant is currently confined to a motorized wheelchair. On April 5, 2010, Dr. M, M.D., Claimant's current treating doctor, requested preauthorization of Baclofen 10 mg. The request was denied and Claimant requested a review. The Texas Department of Insurance appointed (Independent Review Organization), as the Independent Review Organization (IRO). On July 16, 2010, the IRO physician reviewer, Board Certified in Physical Medicine and Rehabilitation - Subspecialty Board Certified in Pain Management, overturned the previous adverse determination and opined that the diagnosis of RSD or CRPD has been accepted, that Claimant had a spinal cord stimulator inserted in the cervical and lumbar region, and that she was confined to a motorized wheelchair. He also noted that medical records revealed ongoing use without an increase in medication use and that there was a pain agreement in effect. He also noted that abrupt discontinuation could lead to hallucinations. The reviewer referenced the ODG section with regard to ANTISPASTICITY DRUGS. Carrier appealed the IRO decision.

Claimant and Dr. M were the only witnesses at the CCH. Claimant testified that she began taking Baclofen in about 2002 after other drugs she had been prescribed failed to relieve her muscle spasms/jerks. She testified that her legs and arms suddenly twitch and that she did not have control over her spasticity. According to Claimant, Baclofen helps control her pain because the more she spasms the worse her pain is. Claimant described how her entire body would shake uncontrollably. Claimant testified that when she takes Baclofen, which is an antispasticity drug, it takes the jerks/jerking away and she does not have the headaches and pain. Claimant testified

that every time the insurance carrier has denied her prescription for Baclofen the spasms and jerking return which increases her pain and decreases the quality of her life. Claimant testified that she has been off Baclofen since February of 2010 and that she cannot even hold and drink from a cup because she shakes too severely. She cannot predict when she will experience the jerks and she has to spend much more time confined to her bed.

Dr. M testified in Claimant's behalf as her treating doctor. He testified that Baclofen is not an abusable controlled substance. Documents in evidence established that Baclofen is not a controlled substance. Dr. M opined that Claimant receives significant health benefits from taking Baclofen because it controls her muscle spasms as a result of her complex regional pain syndrome (CRPS). He testified that when muscle spasms occur they are a trigger for many other things related to CRPS including pain and that the continued use of Baclofen is reasonable and necessary for her compensable injury. Dr. M testified that he concurred with the IRO reviewer and that in all reasonable medical probability Baclofen is necessary treatment for Claimant's compensable injury.

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(t), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division is considered a party 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 a preponderance of the evidence-based medical evidence."

With regard to the medication Baclofen the ODG provides the following:

> Antispasticity: See Muscle relaxants.
> Muscle relaxants: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) See the Low Back Chapter. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Schnitzer, 2004) (van Tulder, 2004) (Airaksinen, 2006) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used in caution with patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions) and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone,and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)
> Classifications: Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. (See, 2008) (van Tulder, 2006).
>
> ANTISPASTICITY DRUGS: Used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries (upper motor neuron syndromes). Associated symptoms include exaggerated reflexes, autonomic hyperreflexia, dystonia, contractures, paresis, lack of dexterity and fatigability. (Chou, 2004)
> Baclofen (Lioresal®, generic available): The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007)
> Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment.
> Dosing: Oral: 5 mg three times a day. Upward titration can be made every 3 days up to a maximum dose of 80 mg a day. (See, 2008)

Carrier presented a peer review dated February 8, 2010, from Dr. O, which stated that "current evidence medicine does not support the long term use of a muscle relaxant. The claimant does not have spasticity, or a spinal cord injury. Therefore, it is recommended this medication be weaned off over a 4-week period."

Dr. B, in a Carrier peer-review opined, "The patient sustained an injury on 6/4/2001. She is diagnosed with RSD. As per medical records dated 4/5/10, she has burning pain, swelling and stiffness. She reports Baclofen provides complete relief of spasms. The injury has occurred more than eight years ago. There was no detailed reassessment of her long-term medication use. There was no mention of for how long she will be taking it. There was no documentation of relevant medication warnings fully considered and described to the patient, potential drug-drug interactions including addictive and/or multiplicative effects of multiple substances. Overall, more information is necessary to determine the need for these medications."

Carrier also presented a peer-review from Dr. S, M.D., who opined that the use of Baclofen in this patient who had no documented clinical condition corresponding to the accepted indication for its use was not certifiable. According to Dr. S, "Per ODG, Baclofen is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Also, current guidelines do not include muscle relaxants as part of medications recommended in CRPS." Dr. S then argued that, "There is no comprehensive medical evaluation to substantiate the diagnosis of CRPS."

Contrary to Carrier's peer reviews, the Chou study referenced in the ODG provides the following:

> **Chou R, Peterson K, Helfand M. Comparative efficacy and safety of skeletal muscle relaxants for spasticity and musculoskeletal conditions: a systematic review. *J Pain Symptom Manage*. 2004; 28:140-75.**
> Department of Medicine, Oregon Health & Science University, Portland, Oregon, USA.
> Skeletal muscle relaxants are a heterogeneous group of medications used to treat different types of underlying conditions: spasticity from upper motor neuron syndromes and muscular pain or spasms from peripheral musculoskeletal conditions. There is fair evidence that baclofen, tixanidine, and dantrolene are effective compared to placebo in patients with spasticity (primarily multiple sclerosis). There is fair evidence that baclofen and tizanidene are roughly equivalent for efficacy in patients with spasticity.

Claimant also presented into evidence as her Exhibit 13, a document entitled "Movement Disorders in Peripheral Nerve Disorders by H. Hooshmand, M.D. According to the document, "Movement disorders" are common in most RSD/CRPS patients. In the extensive studies carried out by Jankovic (Jankovic J., Van Der Linden C., Dystonia and tremor induced by peripheral trauma: predisposing factors: *Journal of Neural Neurosurgery Psychiatry* 1988) movement disorders in RSD have been accompanied by tremor and dystonia. Such movement disorders (tremor dystonia) originate from a peripheral nerve injury with secondary pathologic input to CNS (especially the spinal cord). Blumberg and Janig have reported tremor and other movement disorders in more than 80% of CRPS patients. One of the conclusions was that treatment with Klonopin and Baclofen which exert direct inhibitory effect on anterior and ateriolateral cells of the spinal cord is quite beneficial in RSD patients suffering from tremors.

In the instant case, Carrier has not met its burden of proof of overcoming the IRO determination by a preponderance of the evidence-based medicine.

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) and sustained a compensable 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. Baclofen 10 mg 1 po TID #90 is 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 is proper in the (City) Field Office.

3. The preponderance of the evidence is not contrary to the decision of the IRO that Claimant is entitled to Baclofen 10 mg 1 po TID #90 for the compensable injury of _____.

DECISION

Claimant is entitled to Baclofen 10 mg 1 po TID #90 for the compensable injury of _____.

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 **AMERICAN CASUALTY COMPANY OF READING, PENNSYLVANIA,** and the name and address of its registered agent for service of process is:

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

Signed this 13th day of October, 2010

Cheryl Dean
Hearing Officer