MEDICAL CONTESTED CASE HEARING NO. 12114

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 May 31, 2012 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the claimant is not entitled to a one visit psoas compartment complex block with Botox chemodenervation under fluoroscopic guidance with 5 Botox chemodenervation injections with EMG Guidance for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by SH, ombudsman.

Respondent/Carrier appeared and was represented by NI, attorney.

BACKGROUND INFORMATION

Claimant is a 61 year old male that sustained a work injury on (Date of Injury). Earlier medical records were not furnished. An April 6, 2011 EMG/NCV reflected mild abnormalities suggestive of neuropathy possibly related to the patient's diabetes and also suggestive of a bilateral mid-lumbar radiculopathy. He has recently been under the care of AC, M.D. for pain management for chronic low back pain. That doctor has diagnosed iliopsoas dysfunction and a myofascial pain syndrome. Claimant was provided trigger point injections, botox injections and hydrocodone and cyclobenzaprine.

Dr. C requested preauthorization of the proposed procedure and Carrier's preauthorization reviewing physicians denied the procedure as not medically necessary treatment in an initial review on January 16, 2012 and on reconsideration on January 23, 2012. Claimant appealed to an Independent Review Organization (IRO) and in a Notice of Independent Review Decision dated February 20, 2012, the IRO upheld and agreed with the previous preauthorization denials. The IRO decision stated that there was no indication that Claimant has undergone a trial of physical therapy and that he had had botox before with less than a month of benefit. The decision stated that while botox is now supported by the ODG for back pain, the patient's response to it was subtherapeutic because such treatment should last at least three months to be considered therapeutic.

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 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 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 a preponderance of evidence-based medical evidence."

The ODG treatment protocol for treatment of Low Back – Lumbar & Thoracic (Acute and Chronic) pain with botox injections is as follows:

> Under study for chronic low back pain, if a favorable initial response predicts subsequent responsiveness, as an option in conjunction with a functional restoration program. Considering its high cost and the small differences compared with control treatments, its use should be reserved only for patients with pain refractory to other treatments. There are also potentially significant side effects including death. (De Andrés, 2010) Botulinum neurotoxin is considered for low back pain in this systematic review (Level C). (Naumann, 2008) Paravertebral administration of botulinum toxin A in patients with chronic low back pain may

relieve pain and improve function. Initial data from small trials suggest that botulinum toxin is effective, alleviating back pain in selected patients. On the basis of these promising results, additional study in larger trials is warranted. If approved, the number of trial injections should be limited to one, followed by exercise. A number of studies have evaluated the effectiveness of botulinum toxin type A in the treatment of back and neck pain, and the manufacturer is planning on pursuing FDA approval of botulinum toxin for this indication, but there is currently insufficient scientific evidence of the effectiveness of botulinum toxin in the treatment of back pain. (Foster, 2001) (Difazio, 2002) (Lang, 2004) Group health insurers do not generally cover this treatment for back pain. (Aetna, 2005) (Blue Cross Blue Shield, 2005) Some additional new data suggests that it may be effective for low back pain. (Jabbari, 2006) (Ney, 2006) In a recent double-blind, randomized, placebo-controlled study, administration of botulinum toxin A into paraspinal muscles using a novel technique produced significant pain relief in 60% of patients with chronic, refractory low back pain. A similar yield of 53% was noted in another prospective, randomized, open-label study of 75 patients, with 14 months of follow-up. In this study, an early response predicted later responsiveness, with 91% of the responders continuing to respond to repeat injections. The technique of treatment for both studies included covering the whole length of the lumbar erector spinae with one injection given at each lumbar level regardless of pain, tenderness, or trigger point location(s). The dose per injection site was 50 U (Botox), with the total dose per session not to exceed 500 U. (Jabbari, 2007) Interventional strategies such as botulinum toxin injections are not supported by convincing, consistent evidence of benefit from randomized trials. (Chou, 2008) Revisions to the prescribing information of Botox (Allergan) and Myobloc (Solstice Neurosciences) have been made: A boxed warning now highlights the possibility of experiencing potentially life-threatening distant spread of toxin effect from the injection site after local injection. Changes also have been made to the established drug names to reinforce individual potencies and prevent medication errors. Established name changes for the botulinum toxin products are as follows: Botox (botulinum toxin type A) - onabotulinumtoxinA; Dysport (Medicis Pharm botulinum toxin type A) - abobotulinumtoxinA; Myobloc (botulinum toxin type B) - rimabotulinumtoxinB. (FDA, 2009) BTX-A injection did not significantly reduce visual analog scale scores more than treatment with NaCl or bupivacaine; furthermore, the treatments did not result in a significant improvement of patients' daily life activities or psychologic status. Considering its high cost and the small differences compared with control treatments, its use should be reserved only for patients with pain refractory to other invasive treatments. There are also potentially significant side effects including death. (De Andrés, 2010)

Dr. C testified for the claimant at the hearing. He testified that he was an expert in pain management and has had abnormally successful responses to botox treatment. He testified that botox was the treatment that helped Claimant the most and that he had been treating him since 2005. When asked if he wanted to refer to any specific studies to support his position, the doctor stated that anybody could quote a study, when it is the clinical presentation that is most important. When asked as to whether the proposed treatment was pursuant to the ODG, the doctor responded that "they are just guidelines – that's all they are" – and did not offer further comment.

Carrier presented testimony from LG, M.D., who performed one of the preauthorization reviews in this case. She stated that Claimant had other non-related medical problems that confuse the picture as to what the pain generators actually are, such as a diabetic neuropathy. She stated that a psoas is actually a muscle located in the pelvic/hip area, and that pressure on the sciatic nerve where it passes through the pelvic area could be causing pain and spasms. Dr. G stated that Claimant's medical records reflected that he had undergone other non-botox injections which were of more benefit and provided more long-lasting pain relief, and since his most recent botox injection lasted for less than a month, it was not considered a therapeutic treatment response. Dr. G opined that while the ODG does allow botox treatment for some conditions, that if it is not therapeutic, then its use is not pursuant to the ODG. Claimant was unable to prove by the preponderance of the evidence-based medical evidence that the requested treatment is health care reasonably required for the compensable injury of (Date of Injury). His expert medical witness relied only on his medical expertise and did not attempt to establish that his opinion was based on 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 (Date of Injury), Claimant was the employee of (Employer), Employer.

   C. On (Date of Injury), Employer provided workers' compensation insurance with Facility Insurance Corporation, Carrier.

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

2. Carrier delivered to Claimant and Provider 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 proposed one visit psoas compartment complex block with Botox chemodenervation under fluoroscopic guidance with 5 Botox chemodenervation injections with EMG Guidance 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 IRO that one visit psoas compartment complex block with Botox chemodenervation under fluoroscopic guidance with 5 Botox chemodenervation injections with EMG Guidance is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to one visit psoas compartment complex block with Botox chemodenervation under fluoroscopic guidance with 5 Botox chemodenervation injections with EMG Guidance 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 **FACILITY INSURANCE CORPORATION** and the name and address of its registered agent for service of process is

KATHRYN ANN PLEVICK
2801 VIA FORTUNA, SUITE 400
AUSTIN, TEXAS 78746-7567

Signed this 8th day of June, 2012.

David Wagner
Hearing Officer