

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 held on October 20, 2008, 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 entitled to a lumbar spine Botox injection for the compensable injury of _____?

PARTIES PRESENT

Carrier appeared and was represented by attorney JC. Dr. C, M.D., Respondent, did not appear and did not respond to a 10-day letter. Claimant did not appear and did not respond to a 10-day letter.

BACKGROUND INFORMATION

Carrier is the petitioner in the instant case, and has the burden of proof. The disputed issue is whether the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Claimant is entitled to a lumbar spine Botox injection for the compensable injury of _____.

It is undisputed that Claimant sustained an injury during the course and scope of his employment on _____. Neither Claimant, nor the requesting provider, Dr. C, appeared at the hearing. The only evidence presented was the IRO decision and documents introduced by the Carrier.

In reviewing Dr. C's request for lumbar spine Botox injections, the first utilization review doctor, Dr. B, a pain management doctor, referenced the *ODG* and stated that paravertebral administration of Botox in patients with chronic low back pain was under study. Dr. B stated that "[u]nder the FDA botox has not been approved for use in the lumbar spine but only for cervical dystonia. Under current guidelines this is under study." For these reasons, Dr. B denied the requested treatment.

The utilization review doctor who reviewed the request on reconsideration, Dr. K, a family practice/pain management doctor, also denied the requested lumbar spine botox injections, citing the "under study" categorization of the treatment under the *ODG*. Dr. K cited the Low Back chapter of the *ODG* and opined that the clinical information submitted failed to meet practice guidelines for the services requested. He stated that the "ODG and FDA guidelines do not list low back pain as an approved indication."

A third peer review doctor, Dr. A, opined that the use of Botox or other steroid injections for chronic

low back pain was not indicated.

The IRO reviewer, an osteopath specializing in preventive medicine and occupational and family medicine, overturned the carrier's denial of the requested lumbar spine Botox injection. The reviewer noted that Claimant injured his low back and has had conservative treatment. The treatment included a Botox injection on April 17, 2008, which gave Claimant 70% to 75% relief of pain. According to the treatment notes reviewed by the IRO on September 3, 2008, Claimant "hardly took any medications in the last 90-days until the Botox wore off" and was able to increase his work hours to 25 hours a week. After the injection wore off, Claimant had to reduce his weekly work hours to 14. The reviewer cited the same provisions of the *ODG* relied on by the carrier in denying the requested injection. The reviewer noted that the *ODG* neither "recommended" or failed to "recommend" the treatment as it was under study. The reviewer noted the *ODG* suggestion that further clinical evidence (specifically larger studies) needed to be obtained. The reviewer also noted that in Claimant's case, the treatment had been tried and yielded significant benefit, specifically increased function and work ability and decreased dependence on medication for pain relief. The reviewer opined that Claimant's specific clinical picture was in line with the clinical studies referenced by the *ODG* and overturned the denial of the requested treatment because the treatment had previously been successful in Claimant's case.

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 in any dispute regarding medical necessity is whether the proposed care is consistent with the *ODG*. The carrier argues that the *ODG* does not support lumbar spine Botox injections, while the IRO doctor notes that the procedure is under study and can be used in certain circumstances. It is clear from the evidence presented that at the time of the preauthorization process and subsequent IRO review, the procedure herein was classified by the *ODG* as "under study." That classification has since been amended to recommend the procedure, but the *ODG* cites

the same studies and rationale for the use of Botox injections in the treatment of low back injuries.

The *ODG* Treatment Guidelines discuss lumbar spine Botox injections as follows:

Recommended for chronic low back pain, if a favorable initial response predicts subsequent responsiveness, as an option in conjunction with a functional restoration program. Botulinum neurotoxin may be considered for low back pain (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](#))

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.

In the instant case, the Carrier failed to meet its burden of proof. The treating doctor’s proposed treatment is in accord with the *ODG* and supported by the IRO. The Carrier failed to present evidence-based medical evidence to the contrary. The opinions of the URA and peer review doctors that the *ODG* does not provide for lumbar spine Botox injections are not supported by the evidence-based medicine. Mere citation to the *ODG* does not carry the day. 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*. In the instant case, the IRO opinion is specific and sets out exactly how Claimant’s clinical presentation comports with the *ODG* indications for a lumbar spine Botox

injection. While the use of lumbar spine Botox injections may have been under study at the time of the review in the instant case, that classification has since been removed. The *ODG* cites peer-reviewed studies supporting the use of lumbar spine Botox injections for chronic low back pain where a favorable initial response predicts subsequent responsiveness. The IRO reviewer explained that the clinical evidence in Claimant's case supports the use of those injections for treatment of Claimant's low back injury. Under the Act, treatment provided pursuant to the *ODG* is presumed to be health care reasonably required as mandated by the above-referenced sections of the **Texas Labor Code**. The opinions of the URA doctors and Dr. A are conclusory and do not support a departure from the *ODG* recommendation of the use of Botox injections where a patient has an initial favorable response as Claimant has herein. The carrier's evidence does not meet the requisite evidentiary standard required to overcome the presumption afforded the *ODG*. The preponderance of the evidence is not contrary to the IRO decision and the requested lumbar spine Botox injection for this injured employee meets 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. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.
2. The Division sent a single document stating the true corporate name of the Carrier and the name and street address of Carrier's registered agent for service with the 10-day letter to the Claimant and Respondent, Dr. C, M.D., at their addresses of record. That document was admitted into evidence as Hearing Officer Exhibit Number 2.
3. Claimant and Respondent, Dr. C, M.D., failed to appear for the October 20, 2008, medical contested case hearing and did not respond to the Division's letters offering the parties the opportunity to have the hearing rescheduled.
4. On _____, Claimant was the employee of (Employer) when he sustained a compensable injury.
5. Claimant's treating doctor recommended a lumbar spine Botox injection for treatment of the _____ compensable injury.
6. The IRO determined that the requested services were reasonable and necessary health care services for the compensable injury of _____.
7. The *ODG* indicates lumbar spine Botox injections are appropriate treatment under certain circumstances; and, the requested service is consistent with the *ODG*.
8. The requested lumbar spine Botox injection 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 was proper in the (City) Field Office.
3. The preponderance of the evidence is not contrary to the decision of IRO that a lumbar spine Botox injection is a reasonable and necessary health care service for the compensable injury of _____.

DECISION

Claimant is entitled to a lumbar spine Botox injection 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, PA**, 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 14th day of January, 2009.

Erika Copeland
Hearing Officer