

**DOCKET NO. 453-05-1549.M5
TWCC NO. M5-04-4061-01**

VONO, § **BEFORE THE STATE OFFICE**
Respondent §
§
V. § **OF**
§
TEXAS MUTUAL INSURANCE §
COMPANY, §
Petitioner § **ADMINISTRATIVE HEARINGS**

**DOCKET NO. 453-05-8029.M5
TWCC NO. M5-05-1898-01**

RECEPT PHARMACY. § **BEFORE THE STATE OFFICE**
Respondent §
§
V. § **OF**
§
TEXAS MUTUAL INSURANCE §
COMPANY, §
Petitioner § **ADMINISTRATIVE HEARINGS**

DECISION AND ORDER

VONO and ReCept Pharmacy (Providers) challenged the decisions of two Independent Review Organization (IRO) decisions denying reimbursement for prescription medication provided to two injured workers, ___ and ___ (Claimants). After considering the evidence and arguments of the parties, the Administrative Law Judge (ALJ) concludes that the Providers met their burden of showing that the prescription medication provided to the Claimants was reasonable and medically necessary for Claimants' compensable injuries. Therefore, Providers are entitled to a total of \$4,536.59 in reimbursements from Texas Mutual Insurance Company (Carrier) for the prescription medication in issue.

The hearing convened and closed on April 18, 2006, before Steven M. Rivas, ALJ. Providers appeared and were represented Nicky Otts. Carrier appeared and was represented by Patricia Eads, attorney.

I. DISCUSSION

A. Background Facts

Claimant__ suffered a compensable, work-related injury to his lower back on____. Following his injury, Claimant was treated with various physical therapy modalities, pain medications, and back surgery. Following his back surgery, Claimant's pain complaints persisted, and he was ultimately diagnosed with post-laminectomy syndrome. Claimant's pain medication treatment continued, which included prescriptions for Oxycontin, Hydrocodone, and Duragesic patches. On August 25, 2003, Claimant was prescribed Actiq, a medication designed to treat breakthrough pain. Provider VONO billed Carrier \$1,407.92 for the prescribed medication, which Carrier denied on the basis that it was not medically necessary to treat Claimant's compensable injury.¹

Claimant ____suffered a compensable, work-related injury to her lower back on _____. Following her injury, she underwent various physical therapy modalities, diagnostic tests, and back surgery. Following her back surgery, Claimant was treated with epidural steroid injections, and pain medications for her continued pain complaints. Her pain medications included Duragesic patches, Skelaxin, and Ultracet. On March 22, 2004, and April 8, 2004, Claimant was prescribed Actiq to treat her complaints of breakthrough pain. Provider ReCept billed Carrier \$3,128.67 for the prescribed medication, which Carrier denied on the basis that it was not medically necessary to treat Claimant's compensable injury.²

Each Provider filed a separate request for Medical Dispute Resolution with the Medical Review Division of the Texas Workers' Compensation Commission³. The disputes were sent to two separate IROs, which upheld both of Carrier's denials of reimbursement, and each Provider filed a

¹ Provider initially billed Carrier \$2,109.93 for the medication, which was reduced to \$1,407.92 pursuant to the maximum allowable reimbursement (MAR) rate.

² Provider initially billed Carrier \$3,129.90 for the medication, which was slightly reduced to the MAR rate of \$3,128.67.

³ Effective September 1, 2005, the functions of the Commission have been transferred to the newly created Director of Workers' Compensation within the Texas Department of Insurance.

separate request for hearing before the State Office of Administrative Hearings (SOAH). Due to the similarities of each dispute, including same item in dispute (Actiq) and same type of compensable injury, the disputes were joined and heard simultaneously.

B. Applicable Law

The Texas Labor Code contains the Texas Workers' Compensation Act (the Act) and provides the relevant statutory requirements regarding compensable treatment for workers' compensation claims. In particular, TEX. LAB. CODE ANN. § 408.021(a) 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. The statute further states an employee are specifically entitled to health care that "cures or relieves the effects naturally resulting from the compensable injury, promotes recovery; or enhances the ability of the employee to return to or retain employment."

Under TEX. LAB. CODE ANN. §401.011(19), health care "includes all reasonable and necessary medical aid, medical examinations, medical treatment, medical diagnoses, medical evaluations, and medical services."

C. Evidence

Carrier's main argument was that Actiq was not an appropriate medication for either Claimant because it is a potent narcotic specifically designed to treat breakthrough pain in cancer patients. Carrier asserted Actiq should not be used to treat patients with non-malignant chronic pain conditions. Provider contended that other long-term medications, like Oxycontin and Durgesic, were not bringing sufficient relief for Claimant's breakthrough pain.

Providers' witness, Daniel Boyle, D.O., acknowledged Actiq was approved by the Federal Drug Administration (FDA) as a medication to relieve breakthrough pain in cancer patients. However, Dr. Boyle asserted it is not uncommon for a drug initially designed for one purpose to be used to treat other conditions. Such usage is referred to in the medical community as "off-label."

Dr. Boyle testified that off-label usage is widely practiced and accepted within the medical community and that Actiq is commonly prescribed for such off-label usage by non-cancer patients. Dr. Boyle further testified that in regard to pain medication, he does not prescribe different medication for different areas of pain. For example, Dr. Boyle pointed out that he would not give one type of medication to a patient who complained of toe pain and another type of medication to a patient who complained of back pain. Dr. Boyle stated that regardless of where pain comes from, a herniated disk or cancer, a person's body cannot distinguish which type of medication he or she is given. A person can only feel the effects of medication, according to Dr. Boyle, and that is why off-label usage is commonplace in the medical field.

Dr. Boyle additionally described Actiq as a medication that is taken in the same manner a person eats a lollipop candy, by placing the medication inside the mouth just inside the cheek. Because of this type of ingestion, the medication can be absorbed quickly and be fast-acting. Dr. Boyle also said a patient need not take a full dosage, only an amount that controls the pain.

Provider argued this type of fast-acting, high potent medication was prescribed in order to allow the Claimants the ability to control their pain without rendering them unable to function. Additionally, Dr. Boyle asserted that Claimants' treating doctors made a clinical decision when they prescribed these medications, and it was effective in controlling Claimants breakthrough pain.

Carrier argued Actiq was not medically necessary because of its high propensity for addiction. Both experts called by Carrier, Robert Joyner, M.D., and Clark Watts, M.D., characterized Actiq as a dangerous drug that was not the best choice for either Claimant.

Dr. Joyner testified that the rapidity of onset for drugs like Actiq leads to a potential "buzz" or elevated blood pressure level, which in turn may cause a person to become addicted. Dr. Joyner further testified that other medications like Hydrocodone and Duragesic are more appropriate because they are much less likely to cause true addictive propensities. Additionally, Dr. Joyner noted Actiq carries a "black box warning" from the FDA, meaning there is an inherent danger in using this drug, which may lead to addiction.

D. Analysis and Conclusion

After considering the evidence and arguments presented, the ALJ finds that Providers have met their burden of proving that Actiq was medically necessary for treatment of Claimants' compensable injuries. Although the record indicates that Actiq is intended for cancer patients, the evidence presented by Providers reflects that off-label usage is common and accepted in the medical community.

Carrier's arguments regarding the inappropriateness of Actiq's off-label usage are not persuasive in this instance. The testimony that Actiq may be habit-forming and addictive was not disputed; however, no evidence of addictive behavior was established. This entire dispute covers three dates of service, one for Claimant __in __, and two for Claimant __in__. Following the disputed dates of service, no evidence of further use was noted.

The evidence in this hearing focused on the risks of using Actiq, but the medical records presented in this matter do not portray the Claimants as suffering from addiction or dependency. The ALJ believes that after having been unsuccessful in controlling Claimants' back pain, Providers prescribed a fast acting, highly potent, medication to treat breakthrough pain caused by compensable injuries. While other medications existed, the ALJ believes the prescribed medication met the threshold of being medically necessary to treat Claimants' compensable injuries.

Based on the foregoing, the ALJ believes the Actiq prescriptions rendered to Claimants __and__ were reasonable and medically necessary to treat their compensable injuries. Therefore, Providers VONO and ReCept are entitled to a total of \$4,536.59 reimbursement from Carrier for the prescription medication dispensed to Claimants.

II. FINDING OF FACT

1. Claimant __suffered a compensable, work-related back injury on__.
2. Claimant__ suffered a compensable, work-related back injury on__.

3. Both Claimants underwent various physical therapy modalities, medication treatment, and back surgery.
4. Both Claimants continued to have pain complaints following back surgery.
5. As part of their treatment, Claimants were prescribed the medication Actiq for their breakthrough pain. On August 25, 2003, VONO filled a prescription of Actiq for Claimant J.B. ReCept filled prescriptions of Actiq on March 22, 2004, and April 8, 2004, for Claimant I.M.
6. VONO and ReCept (Providers) billed Texas Mutual Insurance Company (Carrier) the sum of \$4,536.59 for the medication provided to Claimants.
7. Carrier denied reimbursement for the medication, claiming the medication was not reasonable or medically necessary to treat Claimants' compensable injuries.
8. Providers requested medical dispute resolution by the Texas Workers' Compensation Commission's Medical Review Division (MRD), which referred these matters to an Independent Review Organization (IRO).
9. The IRO physician reviewers determined that the medication was not medically necessary for treatment of Claimants' compensable injuries. Providers requested a hearing and the cases were referred to the State Office of Administrative Hearings (SOAH).
10. On October 11, 2005, these matters were consolidated. On February 6, 2006, a notice of the hearing in this case was mailed to the parties.
11. The hearing convened and closed on April 18, 2006, with Administrative Law Judge Steven M. Rivas presiding. Providers appeared and were represented by Nicky Otts. Carrier appeared and was represented by Patricia Eads, attorney.
12. Although Actiq is intended for cancer patients, off-label usage of medication is a common and accepted practice in the medical community.
13. Actiq did not cause either Claimants in this matter to become addicted.
14. Actiq helped control Claimants' complaints of breakthrough pain.
15. Actiq was medically appropriate and necessary for treatment of Claimants' compensable injuries.

III. CONCLUSIONS OF LAW

1. The Texas Workers' Compensation Commission (or its successor agency, the Texas Department of Insurance) has jurisdiction related to this matter pursuant to the Texas Workers' Compensation Act, TEX. LAB. CODE ANN. § 413.031.
2. SOAH has jurisdiction over this proceeding, including the authority to issue a decision and order, pursuant to the Texas Workers' Compensation Act, specifically TEX. LAB. CODE ANN. §413.031(k), and TEX. GOV'T CODE ANN. ch. 2003.
3. The hearing was conducted pursuant to the Administrative Procedure Act, TEX. GOV'T CODE ANN. ch. 2001 and 28 TEX. ADMIN. CODE ch. 148.
4. The requests for a hearing were timely made pursuant to 28 TEX. ADMIN. CODE § 148.3.
5. Adequate and timely notice of the hearing was provided according to TEX. GOV'T CODE ANN. §§2001.051 and 2001.052.
6. VONO and ReCept had the burden of proof in this matter. 28 TEX. ADMIN. CODE §§ 148.21(h) and 133.308(w).
7. VONO and ReCept have shown, by a preponderance of the evidence, that the medication Actiq was medically necessary for treatment of Claimants' compensable injuries. TEX. LAB. CODE ANN. §§ 408.021(a)(1-3) and 401.011(19).
8. VONO is entitled to reimbursement in the amount of \$1,407.92 for the medication Actiq provided to Claimant ___.
9. ReCept is entitled to reimbursement in the amount of \$3,128.67 for the medication Actiq provided to Claimant___.

ORDER

IT IS, THEREFORE, ORDERED that the Texas Mutual Insurance Company is to reimburse VONO the sum of \$1,407.92 and ReCept the sum of \$3,128.67 for the medication Actiq provided to Claimant __ on August 25, 2003, and to Claimant __ on March 22, 2004, and April 8, 2004.

SIGNED June 19, 2006.

**STEVEN M. RIVAS
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS**