

**DOCKET NO. 453-04-5346.M5  
MDR NO. M5-04-0128-01**

**VONO** : **BEFORE THE STATE OFFICE**  
: **OF**  
**V.** : **ADMINISTRATIVE HEARINGS**  
: **STATE OFFICE OF RISK**  
**MANAGEMENT** :

**DECISION AND ORDER**

VONO challenges the decision of the Independent Review Organization (IRO) denying reimbursement for prescription medication provided to injured worker (Claimant). After considering the evidence and arguments of the parties, the Administrative Law Judge (ALJ) concludes that the State Office of Risk Management (SORM) is liable for reimbursing VONO the sum of \$7,368.59 for the prescription medication in issue.

**I. Background**

Claimant suffered a compensable, work-related injury to her lower back in\_\_\_\_. Claimant received significant amounts of treatment over the next nine years, but continued to suffer ongoing chronic pain. In 2002, Claimant was prescribed the medication Actiq for her lower back pain. VONO filled three prescriptions of Actiq for Claimant between September 2002 and November 2002. VONO then billed SORM for the prescriptions. SORM declined reimbursement, asserting that the medical necessity for the prescriptions had not been shown. After VONO requested reconsideration of the denial and provided more information, SORM again denied reimbursement, claiming the medication was not medically necessary.

Based on SORM's denial, VONO sought medical dispute resolution through the Texas Workers ' Compensation Commission (Commission). The matter was referred to an IRO designated by the Commission for the review process. The IRO determined that the medication was not medically necessary treatment for Claimant's compensable injury. VONO then requested a hearing before the State Office of Administrative Hearings (SOAH). The hearing convened and closed on

October 20, 2004, with ALJ Craig R. Bennett presiding. VONO appeared through its designated representative, Nicky Otts. SORM appeared through its attorney, Stephen Vollbrecht. No parties objected to notice or jurisdiction.

## **II. Discussion and Analysis**

This case is rather straightforward. SORM denies the medical necessity of the medication Actiq, asserting that it is a powerful opioid specifically designed to treat breakthrough pain in cancer patients with malignant conditions.<sup>1</sup> SORM argues Actiq should not be used to treat patients with non-malignant chronic pain conditions. In support of its position, SORM presented the drug's fact sheet and other literature regarding the use of Actiq. That documentation shows that Actiq is an oral opioid lozenge that has received FDA approval for the treatment of breakthrough pain in cancer patients. It is intended for use by patients with malignant cancer conditions who are opioid tolerant and who do not benefit from the use of other pain medications. Because of Actiq's FDA approval and designed use, SORM asserts that it was inappropriate and not medically necessary for treatment of Claimant's non-malignant chronic pain condition.

In response, VONO argues that it is common for medications initially designed for one purpose to be used to treat other conditions. Such usage is referred to in the medical community as off-label. VONO presented the testimony of Rick Taylor, D.O., and Nicky Otts, a pharmacist. Both of these witnesses indicated 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. Further, VONO presented the written statement of Claimant's treating doctor, who indicated that Actiq was medically necessary for treatment of Claimant because of her ongoing chronic pain condition.

After considering the evidence and arguments presented, the ALJ finds that VONO has met its burden of proving that Actiq was medically necessary for treatment of Claimant's compensable injury. Although the documentation indicates that Actiq is intended for cancer patients, the evidence

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<sup>1</sup> Breakthrough pain is a sudden and rapidly escalating flare of pain occurring on a background of otherwise well-controlled consistent pain (i.e., a chronic pain condition that lasts 12 or more hours each day).@ Pet. Ex. 3.

presented by VONO indicates that off-label usage is common and accepted in the medical community. Moreover, VONO's evidence shows that the medication was medically appropriate for Claimant's condition. Essentially, SORM's sole argument is that off-label usage of Actiq is simply not appropriate. However, SORM presented no expert testimony or other persuasive evidence showing that off-label usage is not an accepted medical practice. Further, SORM did not present any persuasive evidence showing other reasons why Actiq would not have been appropriate to treat Claimant's condition.

In the absence of controverting evidence, the ALJ finds that VONO's evidence is sufficient to meet its burden of proving that the medication Actiq was medically necessary for treatment of Claimant's compensable injury. Therefore, SORM is liable to reimburse VONO for the three prescriptions in issue. In support of this determination, the ALJ makes the following findings of fact and conclusions of law.

### **III. Findings of Fact**

1. \_\_\_\_ (Claimant) suffered a compensable, work-related injury in\_\_\_\_.
2. The State Office of Risk Management (SORM) is the provider of workers' compensation insurance covering Claimant for her compensable injury.
3. For her compensable injury, Claimant began receiving treatment from Fernando Avila, M.D.
4. As part of his treatment of Claimant, Dr. Avila prescribed the medication Actiq for her. Between September 2002 and November 2002, VONO filled three prescriptions of Actiq for Claimant .
5. VONO billed SORM the sum of \$7,371.60 for the medication provided to Claimant between September 13, 2002 and November 6, 2002.
6. The amount in dispute, based on the maximum allowable reimbursement for the medication discussed in the previous finding, is \$7,368.59.
7. SORM denied reimbursement for the medication.
8. VONO requested medical dispute resolution by the Texas Workers' Compensation Commission's Medical Review Division (MRD), which referred the matter to an Independent Review Organization (IRO).

9. After conducting medical dispute resolution, the IRO physician reviewer determined that the medication was not medically necessary for treatment of Claimant's compensable injury.
10. Based on the IRO decision, MRD issued an order on February 18, 2004, declining to order reimbursement.
11. On March 31, 2004, VONO requested a hearing and the case was referred to the State Office of Administrative Hearings (SOAH).
12. On October 20, 2004, Administrative Law Judge Craig R. Bennett convened a hearing in this case. VONO appeared through its designated representative, Nicky Otts. SORM appeared through its attorney, Stephen Vollbrecht. The hearing concluded and the record closed that same day. No parties objected to notice or jurisdiction.
13. Although Actiq is intended for cancer patients, off-label usage of medication is common and accepted in the medical community.
14. Actiq is designed to treat breakthrough pain, and Claimant suffered such ongoing pain as part of her chronic pain condition resulting from her compensable injury.
15. Actiq was medically appropriate and necessary for treatment of Claimant's compensable injury.

#### **IV. Conclusions of Law**

1. SOAH has jurisdiction over this proceeding, including the authority to issue a decision and order, pursuant to the Texas Workers' Compensation Act, specifically TEX. LABOR CODE ANN. §413.031(k) and TEX. GOV'T CODE ANN. ch. 2003.
2. The hearing was conducted pursuant to the Administrative Procedure Act, TEX. GOV'T CODE ANN. ch. 2001 and 28 TEX. ADMIN. CODE ch. 148.
3. The request for a hearing was timely made pursuant to 28 TEX. ADMIN. CODE §148.3.
4. Adequate and timely notice of the hearing was provided according to TEX. GOV'T CODE ANN. §§2001.051 and 2001.052.
5. VONO has the burden of proof in this matter. 28 TEX. ADMIN. CODE §§148.21(h) and 133.308(w).

6. VONO has shown, by a preponderance of the evidence, that the medication Actiq was medically necessary for treatment of Claimant's compensable injury. TEX. LAB. CODE ANN. § 408.021(a)(1-3) and 401.011(19).
7. VONO is entitled to reimbursement in the amount of \$7,368.59 for the medication Actiq provided to Claimant.

**ORDER**

IT IS, THEREFORE, ORDERED that the State Office of Risk Management is to reimburse VONO the sum of \$7,368.59 plus interest for the medication Actiq provided to Claimant between September 13, 2002, and November 6, 2002.

**SIGNED November 5, 2004.**

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**CRAIG R. BENNETT  
ADMINISTRATIVE LAW JUDGE  
STATE OFFICE OF ADMINISTRATIVE HEARINGS**