SOAH DOCKET NO. 453-05-6381.M5
TWCC MDR NO. M5-05-1771-01

ORTHOPAEDIC INSTITUTE PHARMACY,	§	**BEFORE THE STATE OFFICE**
Petitioner	§	
	§	
v.	§	**OF**
	§	
CONTINENTAL CASUALTY COMPANY,	§	
Respondent	§	**ADMINISTRATIVE HEARINGS**

DECISION AND ORDER

I. SUMMARY

Orthopaedic Institute Pharmacy, the Provider, appealed the decision of Maximus, an independent review organization (IRO), in Texas Workers' Compensation Commission (TWCC)[1] Medical Review Division (MRD) tracking number M5-05-1771-01, denying reimbursement for prescription medication provided to the Claimant. This decision orders that Continental Casualty Company, the Carrier, is not required to reimburse the Provider.

The Administrative Law Judge (ALJ) convened the hearing on January 11, 2006. The hearing was concluded and the record closed that day. The Provider appeared through its representative Nicky Otts and the Carrier appeared through its representative Erin Shanley, attorney.

II. EVIDENCE AND BASIS FOR DECISION

The issue presented in this proceeding is whether the Carrier should reimburse the Provider for filling a prescription for Bextra on February 26, 2004. The Carrier argued that Bextra is not approved by the Food and Drug Administration (FDA) for the treatment of either carpal tunnelsyndrome or flexor tenosynovitis (tendon inflammation), and it should not be required to

[1] Effective September 1, 2005, the functions of TWCC were transferred to the newly created Division of Workers' Compensation of the Texas Department of Insurance.

reimburse the Provider for an off-label use of the drug. The parties asserted that $651.46 is in dispute.[2]

The documentary record consisted of one exhibit presented by the Provider, Pet. Exh. 1 (14 pages), and one exhibit submitted by the Carrier, Res. Exh. 1 (18 pages). Additionally, Rick Taylor, D.O., testified as an expert witness on behalf of the Provider. The Carrier did not offer oral testimony at the hearing, relying solely on the documentation submitted in its exhibit.

The Claimant suffered a work related injury on___. She has a diagnosis of bilateral carpal tunnel and is post-release surgery. In an evaluation conducted on May 7, 2003, the Claimant demonstrated evidence of recurrent tendon inflammation and mild associated carpal tunnel syndrome, and her treating physician prescribed Bextra.[3] A peer review prepared by Theodore Pearlman, M.D., a board certified psychiatrist, stated that the Claimant's injury had resolved by March 26, 1999, even though she claimed persistent left elbow pain. Dr. Pearlman found no objective evidence in the medical records to support the Claimant's subjective pain symptoms.[4] The Carrier denied payment with peer review stating that the prescription was not medically necessary.[5]

Dr. Taylor is certified in pain management and practices in Kerrville, Texas. He reviewed the Claimant's medical records and testified that she is suffering from tendon inflammation. According to Dr. Taylor, Bextra is an anti-inflammatory and was appropriately prescribed to the Claimant. Further, he stated that while treatment of carpal tunnel with Bextra is not listed in the literature, carpal tunnel is caused by inflammation and is commonly treated with Bextra. On cross-examination, Dr. Taylor admitted that an arthritic joint and an inflamed tendon are not the same thing. He stressed though that the inflammatory process is the same in joints, tendons, muscles, and organs.

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[2] Pet. Exh. 1, page 7.

[3] Pet. Exh. 1, page 4 and 11.

[4] Res. Exh. 1, pages 17 and 18.

[5] Res. Exh. 1, page 14.

The Carrier's documentary evidence showed that Bextra is a nonsteroidal anti-inflammatory drug that alters the production of bodily chemicals which promote inflammation of arthritis and cause the pain, swelling, and tenderness of arthritic joints. Bextra is approved for osteoarthritis, rheumatoid arthritis, and the pain of menstrual cramps,[6] and was voluntarily withdrawn from the market.[7]

The ALJ concludes the Provider failed to prove that Bextra was medically necessary and reasonably required to treat the Claimant's injury. While it was Dr. Taylor's opinion that Bextra was appropriately prescribed for carpal tunnel syndrome and tendon inflammation, there was no literature presented supporting that viewpoint. The FDA established the benchmark approval for use of the drug Bextra. The Provider had the burden of proof to show that the non-FDA approved use for the drug was medically necessary. More is needed than the opinion of one doctor to carry the burden of proof. The witness did not refer to any medical literature or studies that tended to support his medical opinion.

III. FINDINGS OF FACT

1. On___, the Claimant was diagnosed with bilateral carpal tunnel syndrome, a compensable injury.

2. The Claimant's injury is covered by workers' compensation insurance written for the Claimant's employer by Continental Casualty Company, the Carrier.

3. The Claimant continues to suffer from recurrent tendon inflammation and mild associated carpal tunnel syndrome.

4. The Claimant was prescribed Bextra for treatment of the symptoms referred to in Finding of Fact No. 3.

5. Orthopaedic Institute Pharmacy, the Provider, filled the Claimant's prescription for Bextra on February 26, 2004.

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[6] Res. Exh. 1, pages 1, 7, and 8.

[7] In April 2005, Pfizer, the manufacturer of Bextra, was asked by the FDA to voluntarily withdraw Bextra from the United States market due to potential increased risk for serious cardiovascular adverse events. Pfizer agreed to suspend sales and marketing of Bextra in the United States, pending further discussion with the FDA.

6. The Carrier denied reimbursement to the Provider for the prescription on the basis that Bextra was not medically necessary to treat the injury.

7. The Food and Drug Administration (FDA) has approved Bextra for the treatment of osteoarthritis, rheumatoid arthritis, and the pain of menstrual cramps.

8. Bextra is a nonsteroidal anti-inflammatory drug that alters the production of bodily chemicals which promote inflammation of arthritis and cause the pain, swelling, and tenderness of arthritic joints.

9. Bextra has not been approved by the FDA for the treatment of tendon inflammation and carpal tunnel syndrome.

10. The Provider did not refer to any medical literature or studies that tended to support the use of Bextra for the treatment of tendon inflammation and carpal tunnel syndrome.

11. The Provider timely requested dispute resolution by the Medical Review Division (MRD) of the Texas Workers' Compensation Commission (TWCC).

12. On April 1, 2005, in MRD Tracking No. M5-05-1771-01, the MRD issued its decision adopting the independent review organization decision concluding that Bextra was not medically necessary, and the Provider timely appealed.

13. TWCC sent notice of hearing to the parties on May 12, 2005. The hearing notice informed the parties of the matter to be determined, the right to appear and be represented by counsel, the time and place of the hearing, and the statutes and rules involved.

14. The hearing on the merits convened January 11, 2006, before Michael J. Borkland, Administrative Law Judge. The Provider appeared through Nicky Otts. The Carrier appeared through Erin Shanley, attorney.

IV. CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction related to this matter pursuant to Acts of May 30, 2005, 79th Leg., R.S., ch. 265, 2005 Tex. Sess. Law Serv. Ch 265 (HB 7) and TEX. LAB. CODE ANN. § 413.031.

2. The State Office of Administrative Hearings has jurisdiction over matters related to the hearing in this proceeding, including the authority to issue a Decision and Order, pursuant to TEX. LAB. CODE ANN. § 413.031 and TEX. GOV'T CODE ANN. ch. 2003.

3. Based on Finding of Fact No. 13, the Notice of Hearing issued by TWCC conformed to the requirements of TEX. GOV'T CODE ANN. §§ 2001.051 and 2001.052.

4. The Provider has the burden of proving by a preponderance of the evidence that it should prevail in this matter. TEX. LAB. CODE ANN. § 413.031.

5. Based on Findings of Fact Nos. 3 - 10, Bextra was not medically necessary for treatment of the Claimant's injury.

6. Based on Findings of Fact Nos. 3 - 10 and Conclusions of Law Nos. 4 and 5, reimbursement for the prescription of Bextra should not be required.

ORDER

IT IS, THEREFORE, ORDERED that Continental Casualty Company is not required to reimburse Orthopaedic Institute Pharmacy for the prescription of Bextra dispensed on February 26, 2004, for treatment of the Claimant.

SIGNED February 13, 2006.

MICHAEL J. BORKLAND
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS