SOAH DOCKET NO. 454-06-0843.P1
DWC NO_____

HIGHMARK CASUALTY INSURANCE COMPANY, Petitioner	§	**BEFORE THE STATE OFFICE**
v.	§	**OF**
TEXAS DEPARTMENT OF INSURANCE, DIVISION OF WORKERS' COMPENSATION, AND DANIEL BOYLE II, D. O., Respondents	§	**ADMINISTRATIVE HEARINGS**

DECISION AND ORDER

Highmark Casualty Insurance Company (Carrier) challenges a medical interlocutory order (MIO) issued by the Texas Department of Insurance, Division of Workers' Compensation (Division), requiring it to pay for certain office visits and medications provided over a ninety-day period. The Administrative Law Judge (ALJ) concludes, under the specific facts of this case, that the requested care is not reasonably required by the nature of the injured worker (Claimant)'s injury. As a result, Carrier should be reimbursed for any payments it has made for this treatment.

I. PROCEDURAL HISTORY, NOTICE, AND JURISDICTION

The MIO was issued on December 9, 2005, pursuant to the Division's Prospective Review of Medical Care (PRM) rules at 28 TEX. ADMIN. CODE (TAC) § 133.650. Carrier filed a timely request for hearing. After one continuance, the hearing convened on July 9, 2007, at the State Office of Administrative Hearings (SOAH), before the undersigned ALJ. Carrier filed post-hearing arguments and evidence on August 7, 2007. Dr. Boyle filed post-hearing arguments on August 13, 2007. The hearing closed on the latter date. Carrier and the Division were represented by counsel, who appeared in person. Daniel J. Boyle, II, D.O., participated *pro se*, by telephone.

SOAH has jurisdiction over this proceeding, including the authority to issue a decision and order, pursuant to TEX. LAB. CODE ANN. §§ 402.073(b) and 413.055 and TEX. GOV'T CODE ANN. ch. 2003.

II. DISCUSSION

A. Background

Claimant suffered an at-work low-back injury on _____, when he picked up a commercial-sized commode. He felt immediate back pain with a burning sensation in his left leg. On October 25, 2000, he underwent a microendoscopic L4-L5 hemilaminotomy with a left L4-L5 foraminotomy; a microendoscopic L4-L5 discectomy with exploration of the L4-L5 disc space; and a L4-L5 left medial facetectomy with left L5 foraminotomy. He has had back pain after his surgeries and has continued to receive medications. He has seen several doctors since his injury, including Dr. Boyle. He received a 14 percent whole person impairment rating on June 4, 2003, with his statutory Maximum Medical Improvement date assigned as July 8, 2002.[1]

Dr. Boyle requested the following care for Claimant: one office visit per month every month to evaluate prescription medications; Narco 10 mg, 1 every 4 to 6 hours for pain, 180 per month for three months (540 pills); Xanax 1 mg., 1 twice a day, 60 per month for three months (180 pills); and Restoril 30 mg, 1 at bedtime, 30 per month for three months (90 pills). On November 21, 2005, Robert Charles Lowry, M.D., performed a prospective review of medical care examination (PRME) on the Claimant and concluded that the care was medically necessary to treat Claimant's condition.[2] After Carrier continued to deny payment, the Division issued the MIO on December 9, 2005, ordering Carrier to provide coverage for the requested care.[3] Carrier timely requested a hearing before SOAH.

[1] Ex. A at 56.

[2] Ex. B at Exhibit 3.

[3] Ex. A at Exhibit 1.

Employees have a right to necessary health care under TEX. LABOR CODE ANN. (Labor Code) §§ 408.021 and 401.011. Section 408.021(a) provides: "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 employee is specifically entitled to health care that: (1) cures or relieves the effects naturally resulting from the compensable injury; (2) promotes recovery; or (3) enhances the ability of the employee to return to or retain employment." Section 401.011(19) of the Labor Code provides that health care includes "all reasonable and necessary medical . . . services."

The Carrier has the burden of proof in this proceeding.[4]

B. Analysis

1. Party Positions

Carrier's primary assertion was that the requested care does not meet the Texas Labor Code standard for health care reasonably required (at times, referred to below as medically necessary) because it is not consistent with evidence-based medicine. As stated above, Labor Code § 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." Labor Code § 401.011(22-a) provides,

> (22-a) "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 practice 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.

[4] TEX. LAB. CODE ANN. § 413.055; 28 TEX. ADMIN. CODE (TAC) § 148.14(a).

Labor Code § 18-a provides,

> (18-a) "Evidence-based medicine" means the use of 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.

In support of its position, Carrier cited two versions of the Official Disability Guidelines (ODG), one that is currently in effect (2007 ODG)[5] and one that was in effect on December 9, 2005 (2005 ODG),[6] when the MIO was issued.

It is undisputed that Narco is an opioid pain medication. The 2007 ODG contains several provisions on opiods. It states, under a provision applicable to acute and chronic low-back pain, including lumbar and thoracic pain, that opioids are not recommended except for short term use for severe cases, not to exceed two weeks. When used only for a time-limited course, opioid analgesics are an option in the management of pain for patients with acute low-back problems. Studies have found no difference in pain relief between non-steroidal anti-inflammatory drugs (NAISDs) and opioids and that the effects of opioid drugs are substantial, including the risk of physical dependence.[7]

In subsequent sections, the 2007 ODG states that for patients taking opioids, the prevalence of life-time substance use disorders has ranged from 36 to 56 percent; that there is no evidence that opioids reduce pain when used as treatments for chronic back pain; and that for chronic back pain, opioids appear to be efficacious for short-term relief, but long-term efficacy is unclear.[8]

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[5] Ex. C.

[6] Ex. D. Pursuant to the ALJ's request, Carrier provided the 2005 ODG to the parties and the ALJ after the hearing. The other parties did not challenge the authenticity of the document. It is admitted into evidence as Ex.D.

[7] Ex. C at 1.

[8] *Id.* at 4. The 2007 ODG said opioids have been recommended for neuropathic pain that has not responded to first-line recommendations. It said opioids are not recommended as first-line therapy. *Id.* at 4-5.

The 2005 ODG said opioids are not recommended, except for short-term use in severe cases and where there is ongoing tissue destruction, such as with cancer. They are not recommended as a primary treatment for musculoskeletal conditions.[9] It said treatment should begin with acetaminophen, aspirin, and NSAIDs, but if those drugs are unsatisfactory, opiods may be added, but not substituted.[10] The guideline said studies have found no difference in pain relief between opioids and NSAIDs and patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDS or acetaminophen.[11]

The Xanax prescription was for anxiety and secondarily as a muscle relaxant. The Restoril prescription was as a sleep aid. It is undisputed that both drugs are benzodiazepines. The 2007 ODG said benzodiazepines are not recommended for long-term use because long-term efficacy is unproven; there is a risk of dependence; and most guidelines limit their use to four weeks.[12] It said chronic use of benzodiazepines is the treatment of choice in very few conditions; tolerance to hypnotic effects develops rapidly; long-term use may actually increase anxiety; and anti-depressants are a more appropriate treatment for anxiety.[13] Prescriptions by doctors for months or years has resulted in large populations of long-term users who have become dependant.[14]

The 2005 ODG did not address benzodiazepines specifically, but did address muscle relaxants. It said muscle relaxants are not recommended for chronic pain, although they can be used for acute pain, and they have not been shown to be more effective than NSAIDs.[15]

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[9] Ex. D at 1.

[10] *Id.* This provision did not say whether it was talking about short- or long-term use.

[11] *Id.*

[12] Ex. C at 1.

[13] *Id.*

[14] *Id.*

[15] Ex. D at 2.

Carrier argued that neither Dr. Boyle nor the Division presented evidence that fit the definition of evidence-based medicine. It contended that Dr. Boyle's testimony was essentially that he and other doctors prescribe the disputed drugs for chronic pain, and that he cited no scientific studies, guidelines, or other recognized authority on the efficacy of these drugs.

Carrier also introduced into evidence two retrospective reviews of the medical necessity of the drugs. Both doctors concluded that continued use of the drugs was not indicated.[16]

Carrier tendered into evidence a February 2001 functional capacity examination of the Claimant in which the physical therapist opined that Claimant appeared to exhibit overall lack of maximum effort during the testing.[17] It tendered into evidence a video surveillance of Claimant in which Claimant was observed jumping in and out of his boat, pushing his truck, jumping off the rear bumper of his vehicle, and carrying boxes and groceries.[18]

Dr. Boyle testified that Narco has relieved Claimant's pain, Xanax has decreased his anxiety, and Restoril has been a sleep aid. Together, that have made it possible for him to function. In his opinion, Claimant cannot function without the drugs. He testified that Claimant tried to return to work on a number of occasions, but has been unable to fulfill job requirements.[19]

Dr. Boyle criticized the retrospective reviews introduced by Carrier as not being based on all the records and as representing treatment that is below the standard of care. Both Dr. Boyle and the Division contended that in-person examination of patients, as was done for Claimant by Dr. Boyle and the PRME doctor, is superior to a paper review.

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[16] Ex. A at 66-76.

[17] *Id.* at 77.

[18] *Id.* at 84-93.

[19] Dr. Boyle stated in an August 13, 2007, letter in response to Carrier's submission of the 2005 ODG, that Claimant was able to return to work with the medication provided, but when Carrier stopped providing the medication, he could no longer work.

Dr. Boyle testified that treatment guidelines are meant to be a guide rather than an absolute statement of whether treatment is appropriate. He does not believe the ODG adequately addresses chronic pain.[20] He said when a medication falls outside a guideline, the doctor typically negotiates with the insurer over the appropriate treatment.

Dr. Boyle also testified that guidelines are based on statements in the Physicians Desk Reference rather than medical care and practice. He explained that it is easier for drug companies to obtain FDA approval of a drug by indicating a limited use, but that does not mean that broader uses are not also legitimate. He said drug companies have studied the short-term, but not long-term use of drugs. He said 60 to 70 percent of prescriptions are for "off label" uses. He said, for example, that a psychiatrist seeing a patient for anxiety or phobic reactions will put the patient on benzodiazepines for life. He stressed that chronic pain patients should not be "just left out to dry."

Dr. Boyle maintained that Claimant is not addicted although he is obviously dependent on the medications for function. As an example of the difference between addiction and dependance, he pointed out that diabetic patients are dependant on insulin, but not addicted.

The Division argued that this is a clear cut case of a patient injury that has resulted in long-term pain. It cited Section 408.021 of the Labor Code as requiring insurers to provide reasonably-required care that cures or relieves the effects of the injury.

The Division and Dr. Boyle argued strongly that any reference to the ODG is inappropriate in this case because the services pre-dated the Texas Department of Insurance (TDI) official adoption of the ODG to determine the need for medical services.

The Division argued that the doctors conducting the retrospective reviews received only the information provided by the Carrier and stressed the fact that these doctors did not personally examine Claimant.

[20] The Division argued that the ODG is not based on studies of patients with long-term pain.

2. Decision

On the basis of statutory law requiring medical necessity to be determined on the basis of evidence-based medicine, the ALJ finds that the services are medically unnecessary. This finding is more of a legal conclusion compelled by controlling statutory law than the usual weighing of evidence for and against the need for particular services. It is based on a determination that the only evidence-based medicine in the record is the 2005 and 2007 ODGs;[21] that those guidelines support Carrier's position; and that the Texas legislature requires medical necessity to be judged on the basis of evidence-based medicine when it is available.

It is undisputed that the drugs are prescribed for Claimant's chronic pain. Concerning Narco, the 2007 ODG says that opioids are not recommended for chronic low-back pain, except for short-term use in severe cases and for management of pain for patients with acute low-back problems. The 2005 ODG says simply that opioids are not recommended except for short-term use in severe cases. Both guidelines said studies have found no difference in pain relief between opioids and NSAIDs.[22]

The 2007 ODG says benzodiazepines (which include Xanax and Restoril) are not recommended for long-term use. The 2005 ODG says muscle relaxants (which include Xanax) are not recommended for chronic pain. It also says muscle relaxers are not shown to be more effective than NSAIDS.

[21] Again, evidence-based medicine means 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." TEX. LAB. CODE ANN. §§ 401.011(18-a).

[22] Both guidelines say long-term use is appropriate for treating pain from a continuing injury, such as cancer.

The Division and Dr. Boyle both vigorously objected to considering the ODG because the disputed services occurred before TDI adopted it for use in determining medical necessity. However, although the ODG does not have the status of a rule in this case, the Texas legislature enacted statutory law, effective September 1, 2005, stating that guidelines and other scientifically-based texts are the best evidence of medical necessity.[23] This decision is based on those statutes.

III. FINDINGS OF FACT

1. A worker (Claimant) suffered an at-work low-back injury ____, when he picked up a commercial-sized commode.

2. Claimant felt immediate back pain with a burning sensation in his left leg.

3. On October 25, 2000, Claimant underwent a microendoscopic L4-L5 hemilaminotomy with a left L4-L5 foraminotomy; a microendoscopic L4-L5 discectomy with exploration of the L4-L5 disc space; and a L4-L5 left medial facetectomy with left L5 foraminotomy.

4. Claimant has had back pain after his surgeries and has continued to receive medications.

5. Claimant has seen several doctors since his injury, including Daniel H. Boyle, D.O.

6. Claimant received a 14 percent whole person impairment rating on June 4, 2003, with his statutory Maximum Medical Improvement date assigned as July 8, 2002.

7. Dr. Boyle requested the following care for Claimant: one office visit per month every month to evaluate prescription medications; Narco 10 mg, 1 every 4 to 6 hours for pain, 180 per month for three months (540 pills); Xanax 1 mg., 1 twice a day, 60 per month for three months (180 pills); and Restoril 30 mg, 1 at bedtime, 30 per month for three months (90 pills).

8. On November 21, 2005, Robert Charles Lowry, M.D., performed a prospective review of medical care examination (PRME) on the Claimant and concluded that the care was medically necessary to treat Claimant's condition.

9. After Carrier continued to deny payment, the Division issued a medical interlocutory order (MIO) on December 9, 2005, ordering Carrier to provide coverage for the requested care.

10. Not more than 20 days after receiving the MIO, Carrier requested a hearing before the State Office of Administrative Hearings (SOAH).

[23] Act of May 29, 2005, 79th Leg., R. S. ch. 265, §§ 3.003, 8.020, 2005 Tex. Gen. Laws 485, 611.

11. All parties received not less than 10 days' notice of the time, place, and nature of the hearing; the legal authority and jurisdiction under which the hearing was to be held; the particular sections of the statutes and rules involved; and a short, plain statement of the matters asserted.

12. All parties had an opportunity to respond and present evidence and argument on each issue involved in the case.

13. The medications prescribed were for Claimant's chronic pain.

14. Narco is an opioid.

15. Xanax and Restoril are benzodiazepines.

16. The current Official Disability Guidelines (2007 ODG) say opioids are not recommended for chronic low-back pain, except for short-term use in severe cases and for management of pain for patients with acute low-back problems.

17. The ODG in effect on December 9, 2005 (2005 ODG), at the time the MIO was issued, says opioids are not recommended except for short-term use in severe cases.

18. Both the 2007 and 2005 ODG state that studies have found no difference in pain relief between opioids and NSAIDs.

19. The 2007 ODG says benzodiazepines are not recommended for long-term use.

20. The 2005 ODG says muscle relaxants (which include Xanax) are not recommended for chronic pain.

21. The 2005 ODG says muscle relaxers are not shown to be more effective than NSAIDS.

IV. CONCLUSIONS OF LAW

1. The State Office of Administrative Hearings has jurisdiction over this proceeding, including the authority to issue a decision and order, under TEX. LAB. CODE ANN. §§ 402.073(b) and 413.055 and TEX. GOV'T CODE ANN. ch. 2003.

2. Adequate and timely notice of the hearing was provided in accordance with TEX. GOV'T CODE ANN. §§ 2001.051 and 2001.052.

3. The Carrier has the burden of proof in this proceeding. TEX. LAB. CODE ANN. § 413.055, 28 TEX. ADMIN. CODE (TAC) § 148.14(a).

4. The medications at issue are not reasonably required by the nature of Claimant's compensable injury. TEX. LAB. CODE ANN. §§ 401.011(18-a) and (22-a) and 408.021.

5. Carrier is not liable for the medications at issue. TEX. LAB. CODE ANN. § 408.021.

ORDER

IT IS ORDERED that Highmark Casualty Insurance Company's appeal, under 28 TEX. ADMIN. CODE § 134.650, of the medical necessity of three office visits, and Norco, Xanax, and Restoril prescriptions provided to Claimant be, and the same is hereby, granted.

SIGNED October 3, 2007.

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JAMES W. NORMAN
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS