SOAH DOCKET NO. 453-05-8606.M2
TWCC MRD NO. M-2-05-1843-01

R.S. MEDICAL,	**§**	**BEFORE THE STATE OFFICE**
PETITIONER	**§**	
	§	**OF**
V.	**§**	
	§	**ADMINISTRATIVE HEARINGS**
STATE OFFICE OF RISK	**§**	
MANAGEMENT, RESPONDENT	**§**	

DECISION AND ORDER

R.S. Medical (Provider) appealed the decision of the Texas Workers' Compensation Commission's (Commission) designee, an independent review organization (IRO), which upheld the denial by the State Office of Risk Management (SORM) of preauthorization of the purchase of a medical device called the RS-4i for use by a workers' compensation claimant (Claimant). The denial was based on its finding that the RS-4i was not medically necessary healthcare. This decision finds that the device is medically necessary healthcare for Claimant and its purchase should be preauthorized.

I. JURISDICTION, NOTICE, AND PROCEDURAL HISTORY

There were no contested issues of jurisdiction, notice or venue. Therefore, those issues are addressed in the findings of fact and conclusions of law without further discussion here.

The hearing in this matter convened February 8, 2006, at the State Office of Administrative Hearings, 300 W. 15th Street, Austin, Texas, with Administrative Law Judge (ALJ) Ann Landeros presiding. The record was left open by agreement so that the written testimony of Provider's witness, Susan Keesee could be filed and admitted, which was done. The record closed February 24, 2006. Provider was represented by its designated employee representative, Patrick Cougill. Deputy General Counsel Red Tripp represented SORM. The Commission did not participate in the hearing.

II. DISCUSSION

A. Background Facts

In___, Claimant sustained an injury to his back compensable under the Texas Workers' Compensation Act (Act). At the time of the compensable injury, SORM was self-insured for workers'compensation coverage. Claimant has undergone multiple back surgeries, including a five-level spinal fusion in 2003. He takes narcotic drugs and muscle relaxants for his chronic back pain. In January 2005, Claimant's pain management doctor, Dennis Karasek, M.D., prescribed the RS-4i, an interferential and muscle stimulator device approved by the FDA for use to relieve chronic pain, for a two-month trial period. Based on Claimant's reports of reduced pain after using the device, Dr. Karasek renewed the RS4i prescription on March 9, 2005, for an indefinite period of use. Because the RS4i is durable medical equipment costing over $500, Provider sought preauthorization of Claimant's purchase from SORM.

SORM denied preauthorization, claiming medically necessity had not been established in Claimant's medical records. In July 2005, the IRO reviewer sustained the denial, writing:

> While reviewing the records, it indicated that the patient had used this device and had reported pain relief, but there are no documented visual analog pain scales or reduction of pain. There is no documented reduction in use of pain medications or other services. There is no indication of increased functioning. Research only shows that the requested RS4i muscle stimulator is comparable to the use of a TENS unit, but there is no compelling research to show its efficacy. With the lack of well-documented, significant reduction of pain medication and/or other utilization of services, there is no medical indication for a muscle stimulator to cope with the individual's pain. Therefore, medical necessity was not established and the denial is upheld. (Prov. Ex. 1, p. 89).

Provider timely appealed the IRO's decision upholding the denial.

B. Evidence

Provider presented the testimony of Claimant and its insurance-relations manager, Susan Keesee, and various documents. Carrier presented documentary evidence and the expert testimony of Joel Wilks, M.D.

1. Provider

Claimant testified that he suffers from constant back pain that is monitored and managed by Dr. Karasek, whom he sees every 2-3 months. Claimant started using the RS4i in January 2005 and states he has obtained significant pain relief with it. Except when traveling, he uses the RS4i twice daily. According to the RS-4i's on-board data memory, Claimant has been using the device regularly as he stated. (Prov. Ex. 1 at 108-119). The relief it affords has improved Claimant's sleep and allowed him to reduce his pain medication usage.

Claimant stated that, when he began using the RS4i, he was taking 60 mg of the narcotic Avinza once a day and 900 mg of the anti-convulsant Neurotin three times a day.[1] Within 1-2 months of first using the RS4i, he was able to reduce his Avinza dose to 30 mg once a day. He does sometimes (2-3 times a week) use Valium (a narcotic) for muscle spasms at night or Tramadol (an analgesic) for breakthrough pain during the day. He credits the RS4i with reducing his need for these medications as well. (Prov. Ex. 1, p. 17).

Claimant stated that he has noticed increased pain, especially at night, when he cannot use the RS4i. Because he only sees Dr. Karasek every couple of months, there was a time lag between the date when he first noticed he needed less pain medication and the date when Dr. Karasek changed the Avinza dose.

[1] Claimant noted that his neurosurgeon, Arnold Vardiman, M.D., prescribed the Neurotin, which is why he did not ask Dr. Karasek about reducing the Neurotin dose.

If he did not have the benefits of the RS4i, Claimant is sure that he would need increased doses of medication to deal with his pain. Before using the RS4i, Claimant had not used a TENS unit nor had physical therapy on a regular basis since his last surgery.

Provider's records contained a document signed in January 2006 by Dr. Karasek that stated he believed Claimant's use of the RS4i had been instrumental in reducing Claimant's pain and muscle spasms and is reasonable and necessary to treat Claimant compensable injury. (Pet. Ex. 1, p. 107). In other, undated records, Dr. Karasek wrote that Claimant had experienced some increased function and decreased pain and improved quality of life from use of the device. (Prov. Ex. 1, p. 16).

In a note dated May 16, 2005, Dr. Vardiman noted that Claimant was "weaning down on his medications under Dr. Karasek's careful care" and "really has made dramatic progress. . . ." (Carrier Ex. 1, p. 114).

Provider's employee Ms. Keesee testified she is a registered nurse whose job includes training on the use of the RS-4i.[2] She is familiar with the Federal Drug Administration's (FDA) approval process as it relates to the device. As shown in the FDA's approval letter for the device, it is approved for use to relieve and manage chronic pain. (Prov. Ex. 2).

2. SORM

Dr. Wilks, who was a surgeon but has been the senior medical director for Forte utilization review company since 2000, testified that the RS4i was not shown to be medically necessary for Claimant. Dr. Wilks stated that Claimant was not shown to have muscle atrophy that would benefit from the device's electronic muscle stimulator and the documentation lacked objective measures of reduced pain, such as reduced usage of pain relieving medications. Although Dr. Wilks found the

[2] By agreement of the parties, a transcript of Ms. Keesee's testimony from an unrelated case on the same subject matter was admitted into the record in this hearing.

medical records contained some claims to increased activity by Claimant, the records lacked objective measurements of functional improvement. However, he admitted that improvement in the range of motion in Claimant's back is unlikely.

For the trial usage period from January 17 to March 9, 2005, Dr. Wilks could find no documented improvement in Claimant's condition. He noted that Dr. Vardiman wrote, on

C. Legal Standards

Provider has the burden of proof in this proceeding. 28 TAC §§ 148.14; 1 TAC 155.41. Pursuant to the Act, an employee who has sustained 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 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. TEX. LAB. CODE ANN. § 408.021(a). Health care includes all reasonable and necessary medical services including a medical appliance or supply. TEX. LAB. CODE ANN. §401.011(19)(A). A medical benefit is a payment for health care reasonably required by the nature of the compensable injury. TEX. LAB. CODE ANN. §401.011(31). The IRO was authorized to hear the medical dispute pursuant to 28 TAC §133.308.

For a carrier to be liable for reimbursement of durable medical equipment, the DME must be preauthorized unless the item costs less than $500. 28 TAC § 134.600(h)(11). Preauthorization is a prospective approval obtained from the insurance carrier by the requestor or injured employee prior to providing the health care treatment or services. 28 TAC 134.600(a)(5).

D. Analysis

Provider met its burden of proof to show that the RS-4i is medically necessary healthcare for Claimant and should be preauthorized. Claimant testified that the RS-4i reduces his pain. One

objective measurement of the efficacy of the device is that Claimant is able to reduce his use of pain relievers when he uses the RS-4i. A medical device that reduces the pain from a compensable injury is medically necessary healthcare as defined in TEX. LAB. CODE ANN. § 408.021(a).

SORM correctly noted that Claimant's medical records contained scant documentation of Claimant's reduced use of medication to show the RS4i's efficacy. However, Claimant explained that he only saw Dr. Karasek every 2-3 months so that Claimant's prescriptions were only altered at those time intervals. After Claimant began using the RS4i, Dr. Karasek's first opportunity to change Claimant's medication dosage occurred in March 2005. Despite his prescription dosage, Claimant reduced his intake of Avinza within a month or so of beginning to use the RS4i and has also been able to reduce his Valium and Tramadol use. These reductions in medication use are objective evidence supporting Claimant's subjective reports of pain relief. Given Claimant's back was fused at five levels, conventional range of motion tests are not available as an objective indicator of improved functionality so SORM's desire for this type of objective measurement is simply not possible in Claimant's case.

Provider met its burden to show that the RS4i is medically necessary healthcare for Claimant. Claimant's purchase of the RS4i should be preauthorized.

III. FINDINGS OF FACT

1. Claimant sustained a compensable injury in___.

2. At the time of the injury, the State Office of Risk Management (SORM) was self-insured for workers' compensation insurance coverage for Claimant.

3. Claimant underwent a five-level spinal fusion in 2003.

4. Claimant suffers from chronic low back pain for which he takes the anti-convulsant Neurotin and the narcotic Avinza daily. He also takes the narcotic Valium and the analgesic Tramadol for breakthrough pain and muscle spasms.

5. In January 2005, Claimant's pain management specialist, Dennis Karasek, M.D., prescribed an RS4i interferential stimulator device for Claimant to use on a trial basis.

6. In January 2005, RS Medical (Provider) provided an RS-4i device to Claimant.

7. Since January 2005, Claimant has regularly used the RS-4i device, which has reduced his pain.

8. In March 2005, Dr. Karasek prescribed the RS-4i for Claimant to use indefinitely.

9. Within about a month of beginning to use the RS-4i, Claimant was able to reduce his Avinza dosage from 60 mg per day to 30 mg per day and found his episodes of break-through pain were reduced, thus reducing the amount of Valium and Tramadol he used.

10. When he is unable to use the RS-4i, Claimant experiences increased pain.

11. With use of the RS-4i, Claimant is able to sleep better and increase his activities of daily living.

12. The RS-4i has relieved the pain of Claimant's compensable injury.

13. The RS-4i is an item of durable medical equipment costing over $500 that is medically necessary for Claimant.

14. The RS-4i is approved by the Federal Drug Administration for use to relieve chronic pain.

15. The RS-4i operates in two sequential modes, interferential (two electric current frequencies interfere with each other to produce an electric signal that may block nerve pain) and muscle stimulator (which mechanically moves the muscles to improve tone, function, and blood circulation).

16. After Dr. Karasek wrote the prescription, Provider sought preauthorization from SORM for Claimant's purchase of the RS-4i.

17. SORM denied Provider's preauthorization request.

18. Provider appealed the denial to the Commission, which referred the appeal to an IRO. The IRO upheld SORM's denial of preauthorization.

19. Provider timely appealed the IRO decision.

20. Pursuant to the Commission Staff's notice of hearing, all parties appeared or were represented at the hearing held February 8, 2006.

IV. CONCLUSIONS OF LAW

1. The Texas Workers' Compensation Commission (Commission) has jurisdiction over this matter pursuant to the Texas Workers' Compensation Act (Act), TEX. LAB. CODE ANN. § 413.031.

2. The State Office of Administrative Hearings has jurisdiction over this proceeding, including the authority to issue a decision and order, pursuant to § 413.031(d) of the Act and TEX. GOV'T CODE ANN. ch. 2003.

3. The IRO was authorized to hear the medical dispute pursuant to 28 TEX. ADMIN. CODE (TAC) § 133.308.

4. The hearing was conducted pursuant to the Administrative Procedure Act, TEX. GOV'T CODE ANN. ch. 2001 and the Commission's rules, 28 TAC § 133.308(u).

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

6. Provider had the burden of proof in this proceeding. 28 TAC §§ 148.14; 1 TAC § 155.41.

7. Pursuant to the Act, an employee who has sustained 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 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. TEX. LAB. CODE ANN. § 408.021(a).

8. Health care includes all reasonable and necessary medical services. TEX. LAB. CODE ANN. § 401.011(19)(A). A medical benefit is a payment for health care reasonably required by the nature of the compensable injury. TEX. LAB. CODE ANN. § 401.011(31).

9. For a carrier to be liable for reimbursement of durable medical equipment, the DME must be preauthorized unless the item costs less than $500. 28 TAC §134.600(h)(11) .

10. Preauthorization is a prospective approval obtained from the insurance carrier by the requestor or injured employee prior to providing the health care treatment or services. 28 TAC 134.600(a)(5).

11. The RS-4i is reasonable and medically necessary healthcare for Claimant and its purchase from Provider should be preauthorized.

ORDER

It is ORDERED that the durable medical equipment known as the RS-4i, an interferential

and muscle stimulator device provided by RS Medical, is medically necessary healthcare and is preauthorized for purchase by Claimant.

SIGNED March 10, 2006.

ANN LANDEROS
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS