DOCKET NO. 453-05-7317.M2 TWCC MR NO. M2-05-1466-01

STATE OFFICE OF	§	BEFORE THE STATE OFFICE
RISK MANAGEMENT, Petitioner	§	
	§	
VS.	§	\mathbf{OF}
	§	
	§	
RS MEDICAL, Respondent	§	ADMINISTRATIVE HEARINGS

DECISION AND ORDER

The State Office of Risk Management (SORM) requested a hearing to contest an Independent Review Organization (IRO) determination that the purchase of an RS-4i Sequential Stimulator (RS-4i) is medically necessary and should be authorized for treating at-work injuries suffered by an injured worker (Claimant). This decision concludes that the RS-4i is medically necessary and the purchase should be authorized.

I. PROCEDURAL HISTORY

A hearing was held on February 7, 2006, before the undersigned Administrative Law Judge (ALJ) at the State Office of Administrative Hearings, Austin, Texas. SORM appeared and was represented by Deputy General Counsel, J. Red Tripp. RS Medical appeared and was represented by Patrick K. Cougill. As there were no issues concerning notice or other jurisdictional issues, those matters are addressed in the findings of fact and conclusions of law without further discussion here.

II. DISCUSSION

1. Background

The Claimant's injury occurred on_____, when she slipped and fell in her employer's mailroom, hitting a support beam and a work table on her way down. This has resulted in ongoing pain to her left shoulder and left knee.

The IRO decision, issued on March 23, 2005, concluded that the RS-4i is medically necessary based in part on the following rationale:

.... The recorded evidence indicates a decrease in symptomatology, decrease in pain medications, greater ability to function at work, and enhanced sleep, without any adverse effects from the device being noted. There is nothing in the records to indicate that the physician or the claimant are exaggerating the benefits or are being untruthful as to the benefits. Therefore, the reviewer's conclusion is that it is perfectly reasonable and medically necessary for this claimant to continue to use this device indefinitely.¹

Employees have a right to necessary health treatment under Tex. Labor Code Ann. §§1408.021 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"

As Appellant, SORM had the burden of proof.²

B. Parties Evidence and Arguments

The ALJ concludes that SORM failed to prove the RS-4i is medically unnecessary for treating the Claimant's condition.

SORM's primary evidence was from Joel Wilk, M.D., a Senior Medical Director at Forte, a company whose responsibilities include reviewing the necessity of medical care. Prior to going to work for Forte in September 2000, Dr. Wilk was a general surgeon, ran an outpatient clinic, and was involved in treating injured workers under the workers' compensation system.

Dr. Wilk testified, in determining the efficacy of a device, one looks for more than a patient's subjective assertion of pain decrease. He acknowledged that a patient's subjective view of his or her

¹ Ex. 2 at 105-106.

² 1 Tex. Admin. Code (TAC)§155.41; 28 TAC §148.14.

pain level should not be ignored, but he would put more stock in objective data on the Claimant's pain medication usage and range of motion (ROM) testing than on her subjective pain reports.

Dr. Wilk said he saw no increased ROM or decrease in medications paid for by SORM through January 2005.³ He noted a Texas Workers' Compensation Commission Work Status Report showing the Claimant's medications as steroid shots, Ultracet, Flexoril, Hydrocodone, and Ibuprofen.⁴ He said the report shows her pain medications had not changed.

Dr. Wilk noted that the Claimant underwent trigger point injections for pain relief. He testified he would not expect these injections to be necessary if the RS-4i were relieving her pain. He acknowledged, however, that it is not unusual to employ more than one pain-relief modality at the same time.

Dr. Wilk cited scientific papers comparing the RS-4i to a TENS unit. The papers compared the efficacy of the two devices on the basis of several different pain stimuli. He indicated they found no difference in effectiveness between the devices. He asserted the RS-4i is similar to a TENS unit and was approved by the United Stated Federal Drug Administration (FDA) on that basis. He maintained, however, that the RS-4i costs about four times as much as a TENS unit and asserted that a TENS unit has not been shown to be effective in treating chronic pain.

SORM argued there is no objective evidence that the RS-4i does more than a TENS unit. It maintained there has been no evidence of objective change in the Claimant's condition from its use. It asserted that the records show the Client took the same medications she took before she began using the device.

RS Medical insurance relations manager Susan Keesee testified that the RS-4i was not approved by the FDA as being similar to a TENS unit, as Dr. Welk testified, but as similar to

³ SORM discontinued payment of medications in January 2005 based on its determination that they were no longer medically necessary.

⁴ Ex. 1 at 323. SORM contended that the report was issued on April 22, 2005. However, that date is the date for the next appointment. The date of the report appears to be March 25, 2005. Ex. 1 at 322.

previous interferential devices.⁵ She said an interferential device is different from a TENS unit because it involves two electrical signals of different frequencies that interfere with each other. She said an interferential device has less skin resistence and for that reason, is thought to penetrate more deeply. She pointed out that the RS-4i is also, in part, a muscle stimulator.⁶

The Claimant testified she received the Stimulator in November 2004. She said using it on her shoulder during her lunch hour each day at work helps her get through the afternoons and has made it possible for her to stop using Ultracet, a pain-relieving medication. She believed she stopped using Ultracet in early 2005. She still takes Hydrocodone each morning and evening for her knee. She tries to take the RS-4i home for use during the weekends. She said the RS-4i improves ROM around her waist at desk level. However, it does not help sufficiently to improve her ROM around her shoulders and above her head. RS Medical argued there is no reason to question the Claimant's credibility.

C. <u>Analysis</u>

The ALJ concludes the preponderant evidence indicates the RS-4i is reasonably required by the nature of the Claimant's injury. Her testimony that it relieves her pain was believable. One of the prime indicators of the need for medical care, according to Dr. Wilk, is objective evidence of its efficacy. There is objective evidence of decreased drug usage, particularly Ultracet. Contrary to SORM's assertion, the records show decreased drug usageBthe March 2005 record shows her current medications as Ultracet, steroid shots, Flexeril, Hydrocodone, and Ibuprofen, but also shows that Ultracet and other drugs being discontinued and replaced with Lexapro, Ibuprofen, and Hydrocodone. The Claimant's doctors also said the RS-4i significantly helped and reduced her need for pain medications such as Ultracet. Subsequent records indicate that she continued the Lexapro,

⁵ Ms. Kessee testified she holds certificates indicating expertise on electro-therapy devices. She is the author of a continuing education course on electro-therapy for registered nurses that has been approved by the Texas Board of Nurse Examiners.

⁶ Dr. Welk agreed that a muscle stimulator is different from a TENS unit.

⁷ As indicated above, SORM stopped approving her medications in January 2005. The Claimant testified she paid for her own medications after that time.

⁸ Ex. 1 at 323.

Although there are no objective tests showing ROM improvement, the preponderant evidence shows that the RS-4i decreases her pain sufficiently to give some ROM improvement at the waist level. Her doctor reported that the device helps the Claimant complete her work tasks.¹¹

The Claimant's own experience and the reports of the doctors that examined and treated her are more persuasive than the studies Dr. Welk referred to in his testimony, and Ms Kessee's testimony was persuasive that the FDA views the two devices as distinct.

IV. FINDINGS OF FACT

- 1. The Claimant's injury occurred on____, when she slipped and fell in her employer's mail room, hitting a support beam and a work table on her way down.
- 2. The Claimant's injury has resulted in ongoing pain to her left shoulder and knee.
- 3. The Claimant's doctor prescribed an RS-4i Sequential Stimulator (RS-4i) in November 2004 for pain relief.
- 4. RS Medical is the maker and distributor of the RS-4i.
- 5. The State Office of Risk Management (SORM) paid for renting the device from November 2004 until January 2005.
- 6. In January 2005, the Claimant's doctor prescribed the purchase of the RS-4i.
- 7. SORM denied the claim.
- 8. RS Medical requested medical dispute resolution.
- 9. An independent review organization (IRO) concluded on March 23, 2005, that the RS-4i was medically necessary.
- 10. It is undisputed that SORM requested a hearing not later than the 20th day after it received notice of the IRO decision.

⁹ Ex. 2 at 106., 111.

¹⁰ Ex. 1 at 325, 327, 329, 331, and 333.

¹¹ Ex. 2 at 106.

- 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 RS-4i helps reduce the Claimant's pain.
- 14. The RS-4i has reduced the Claimant's need for pain medications, particularly Ultracet.
- 15. The RS-4i has helped improve the Claimant's range of motion at the waist level and this has aided her in completing her work tasks.
- 16. The RS-4i is reasonably required by the nature of the Claimant's injury.

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. Tex. Lab. Code Ann. §413.031(k) and Tex. Gov't Code Ann. ch. 2003.
- 2. All parties received adequate and timely notice of the hearing. Tex. Gov't Code Ann. §2001.052.
- 3. SORM has the burden of proof. 28 TEX. ADMIN. CODE § 148.14(a).
- 4. The RS-4i is medically necessary. TEX. LAB. CODE ANN. §§ 401.011 and 408.021.
- 5. RS Medical's request for authorization of the Claimant's purchase of the RS-4i should be approved. Tex. Lab. Code Ann. §\$401.011 and 408.021.

ORDER

IT IS, THEREFORE, ORDERED that the request by RS Medical for authorization of the purchase of a RS-4i Sequential Stimulator for use by the Claimant and covered by the State Office of Risk Management be, and the same is hereby, granted.

IT IS ORDERED FURTHER that the State Office of Risk Management shall pay for the RS-4i Sequential Stimulator for use by the Claimant.

SIGNED February 2006.

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