SOAH DOCKET NO. 453-04-1018.M2
TWCC MR NO. M2-03-1813-01

RS MEDICAL,	§	**BEFORE THE STATE OFFICE**
Petitioner	§	
	§	
V.	§	
	§	**OF**
ASSOCIATION CASUALTY	§	
INSURANCE COMPANY,	§	
Respondent	§	**ADMINISTRATIVE HEARINGS**

DECISION AND ORDER

I. DISCUSSION

RS Medical requested a hearing to contest an independent review organization (IRO) determination that preauthorization of a RS 4i Sequential Stimulator (RS 4i Stimulator) for indefinite use by an injured worker (Claimant) should be denied. This decision concludes the RS 4i Stimulator was not shown to be medically necessary.

A hearing convened on April 7, 2004, before Administrative Law Judge (ALJ) James W. Norman at the State Office of Administrative Hearings, Austin, Texas. Patrick K. Cougill represented RS Medical. Tommy W. Lueders represented Association Casualty Insurance Company (Association Casualty). Susan Keesee, RS Medical's Insurance Relations Manager, and Claimant testified for RS Medical. Leonard Hershkowitz, M.D., testified for Association Casualty. There were no contested issues of notice or jurisdiction. The record closed on April 13, 2004, with the submission of additional documentation.

A. Background

The Claimant, a fifty-nine year old male, sustained an at-work injury to his upper back on _____. His diagnosis was herniated thoracic discs at several levels with radiculopathy. This caused thoracic and right shoulder pain. In April 2003, his doctor, Scot J. Frost, M.D., prescribed the

RS 4i Stimulator for two months to reduce muscle spasms and chronic pain. In June 2003, Dr. Frost prescribed the device for an indefinite period for the same purposes.

The United States Food and Drug Administration (FDA) has cleared the RS 4i Stimulator to relieve acute pain and relieve and manage chronic pain.[1] The FDA said, The RS-4i family is substantially equivalent to its legally marketed predecessor the RS-4M+ (K000114) muscle stimulator.[2]

Association Casualty did not contest the efficacy of the RS 4i Stimulator for use during the acute phase of an injury. The only issue in this proceeding is whether the device is reasonable and medically necessary for the Claimant as of the date of the hearing.[3]

Employees have a right to necessary health treatment under TEX. LABOR CODE ANN. §§ 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.

As Appellant, RS Medical had the burden of proof.[4]

B. Testimony and Contentions

1 Ex. 6 at 3 and 5. The device was also cleared for muscle stimulation for relaxing muscle spasms, preventing or retarding disuse atrophy, maintaining or increasing range of motion, increasing local blood circulation, re-educating muscles, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

2 *Id.* at 4.

3 The ALJ adopts the reasoning in SOAH Docket No. 453-03-4229.M2, MDR No. M2-03-1308-01; *RS Medical v. City of El Paso* (January 6, 2004), that the issue of medical necessity is present need, as of the date of the hearing, rather than past need, as of the date of the prescription.

4 1 TEX. ADMIN. CODE (TAC) ' 155.41; 28 TAC ' 148(h).

1. RS Medical

Dr. Frost wrote in a letter dated October 16, 2003,[5] the only evidence that the stimulator works is [*sic*] in this case is that it has been working when epidural steroids and other treatments have not.

In a March 16, 2004, response to RS Medical,[6] Dr. Frost said he believes patients achieve an ongoing benefit from the device; the device is continuing to reduce the pain and muscle spasms that resulted from the Claimant's compensable injury; and it is reasonable and necessary for the claimant to use the device. He does not believe that patients achieve benefits from the device only through the acute phase following an injury.

Ms. Kessee testified that the interferential current portion of the RS 4i Stimulator is a unique modality that is different from other types of electrotherapy.[7] It involves simultaneous two-medium-frequency electrical signals into the body that cross, or interfere, with one another. She said this causes a pulsing wave that very effectively reduces pain. According to Ms. Kessee, medium interferential frequency minimizes skin resistance and allows much deeper penetration. This distinguishes it from a TENS unit, which is a low-frequency device that meets significant skin resistance. She said the device has three pain-relief mechanisms compared to a TENS unit, which has only one.

According to Ms. Kessee, the Philadelphia Panel Physical Therapy Study (Philadelphia study), cited by Association Casualty's experts, reviewed TENS devices, not interferential devices. Ms. Kessee cited a study by Anthony Yeung entitled, Effect of Sequential Elective Surface Stimulation on Medication Utilization Following Selective Endoscopic Discectomy, in the *Journal*

5 Ex. 9 at 1.

6 Ex.10.

7 Ms. Kessee was not shown to be a medical expert.

of Minimally Invasive Spinal Technology. Dr. Yeung concluded there was significantly reduced drug consumption by patients using the RS 4i Stimulator after minimally invasive back procedures.

The Claimant testified that the RS 4i Stimulator has significantly helped reduce pain and swelling in a muscle on the right side of his spine. He said he attended an out-of-state funeral several months ago and did not take the device. According to his physical therapist, the muscle had significantly swelled, but reduced again when he began using the RS 4i Stimulator. The Claimant said he first used a TENS unit and this reduced pain too, but not as much as the RS 4i Stimulator. He said he uses the device once a day. He believes the pain will not go away, but the RS 4i Stimulator helps control the pain.

There are several reports in the evidentiary record showing the Claimant's use of the RS 4i Stimulator. In May 2003, he used it on 23 days for a total of 35 times.[8] In June, he used it on 15 days for a total of 28 times.[9] In July, he used it on four days for a total of nine times.[10] In August, he used it on 10 days for a total of 17 times.[11] In September, he used it on seven days for a total of 14 times.[12] In October, he used it one time on one day.[13] There were no records for November and December 2003 and January 2004. In February, he used the device two times on one day.[14] In the first three weeks of March 2004, he used it on 10 days for a total of 24 times.[15] In a patient health survey conducted in June 2003, the Claimant said he used the device twice each day.[16] In a May

8 Ex. 2 at 6.

9 Ex. 2 at 8.

10 Ex. 8 at 6.

11 Ex. 8 at 4.

12 Ex. 8 at 2.

13 Ex. 11 at 4.

14 Ex. 11 at 3.

15 Ex. 11 at 2.

16 Ex. 12 at 2.

2003 survey, he said he used it one time a day.[17]

RS Medical introduced testimonials from several sports teams extolling the use of the RS 4i Stimulator.[18] Many said they used the device for chronic pain relief as well as in the acute phase following an injury.[19]

RS Medical argued there is no basis to conclude the Claimant's testimony is not credible. It contended that the IRO doctor ignored the FDA clearances, which found the device to be useful in relieving chronic pain. It asserted that the FDA does not issue clearance letters without grounds for doing so.

2. Association Casualty

Leonard Hershkowitz. M.D., a board-certified neurologist, testified on behalf of Association Casualty. He said the interferntial current is like two TENS units set to interfere with one another.

He acknowledged that the unit is said to give a deeper penetration than a TENS unit alone. He indicated the RS 4i Stimulator is a passive modality that is legitimately used in the acute phase, or first six to eight weeks, following an injury or at the latest in the subacute phase.

Dr. Herschkowitz agreed with other reviewers' opinions that the device is inappropriate for use by the Claimant more than two and one-half years after his injury. He said although he would always factor in patient statements about care, he would also need objective evidence on how a device is working. He explained there is a well-recognized, large placebo effect that patients may receive from treatments that actually have no objective value. He said he would expect to see, in written progress notes, such objective measures as an analog pain scale, what a patient could do by

17 Ex. 2 at 5.

18 Exs. 7 and 13.

19 Ex. 7 at 7 and 8; Ex. 13 .

using the device, or medication reductions. He referred to this as evidence-based medicine, and cited it as the medical standard for determining medical necessity.

Dr. Herschkowitz's concern is an absence of medical records for the Claimant demonstrating the efficacy of the device. He said he has not seen adequate information to conclude it is medically necessary at this stage of his injury, but agreed that if it does relieve pain, it could be appropriate.

Dr. Herskowitz referred to the Philadelphia study, which concluded that devices such as electrical stimulators are not helpful after the acute phase of an injury. He agreed that the study did not mention the interferential modality, but said the RS 4i Stimulator is similar to a TENS unit, which was discussed. He has not seen any studies or other evidence to recommend electrical stimulation after the acute phase.

The IRO doctor said that medical literature does not recommend electrical stimulation for chronic back pain. The doctor cited the Philadelphia study as finding little or no supporting evidence for an electrical stimulator for chronic pain greater than six weeks post-injury.[20]

A peer review provided to Association Casualty said passive modalities like the RS 4i Stimulator are recognized in the acute phase of an injury, but not in the chronic. The doctor cited the Philadelphia study as finding little or no supporting evidence to include such modalities in the treatment of chronic pain greater than six weeks post-injury.

Association Casualty said it would not disregard subjective reports from patients, but argued there is insufficient objective medical documentation in this case to show the device is medically necessary. It argued that no one knows the condition the Claimant would be in without the device.

B. Analysis

The ALJ concludes that RS Medical did not carry its burden of proving the RS 4i Stimulator

20 Ex. 5 at 2.

was medically necessary as of the date of the hearing. RS Medical's primary evidence on the need for the device is based on the Claimant's subjective report on the need for the device. Dr. Frost also appeared to rely on the Claimant's subjective reports. Yet, according to the records, the Claimant's use of the device has been very inconsistent, ranging from a high of 23 days for a total of 35 times in May 2003, to lows of one time on one day in October 2003 and two times on one day in February 2004. There were no reports of use for November 2003 through January 2004. It was only in the month before the hearing, in March 2004, that the Claimant's use of the device again picked up. None of the records support the Claimant's assertion that he uses the device every day.

There is also evidence that the Claimant may be experiencing primarily a placebo effect from the RS 4i Stimulator. The Claimant said he used a TENS unit before using the RS 4i Stimulator and the TENS unit also provided relief, although not as much as the RS 4i Stimulator. The ALJ believes the best evidence of the efficacy of a TENS unit on chronic pain was the Philadelphia study, an extensive report that concluded was not effective. If the Claimant experienced a placebo effect from using a TENS unit, it is reasonable to assume he has had the same experience with the RS 4i Stimulator.

In addition to the above-stated considerations, there is insufficient objective evidence to satisfy the evidence-based standard for finding medical necessity discussed by Dr. Herschkowitz.

Overall, the ALJ concludes that RS Medical did not prove by a preponderance of the evidence that the RS 4i Stimulator is reasonably required by the nature of the Claimant's injury.

II. FINDINGS OF FACT

1. The Claimant, a fifty-nine year old male, sustained an at-work injury to his upper back on _____.

2. The Claimant's diagnosis was herniated thoracic discs at several levels with radiculopathy, which caused thoracic and right shoulder pain.

3. In April 2003, the Claimant's doctor, Scot J. Frost, M.D., prescribed the RS 4i Stimulator for two months to reduce muscle spasms and chronic pain.

4. In June 2003, Dr. Frost prescribed the RS 4i Stimulator for an indefinite period. On his prescription, he indicated the device reduced muscle spasms and pain.

5. Association Casualty denied RS Medical's claim and an independent review organization upheld the denial.

6. It is undisputed that RS Medical requested a hearing not later than the twentieth day after receiving notice of the IRO decision.

7. Association Casualty did not contest the efficacy of the RS 4i Stimulator for use during the acute phase of an injury.

8. There are several reports showing the Claimant's use of the RS 4i Stimulator.

    1. In May 2003, the Claimant used the device on 23 days for a total of 35 times.

    2. In June, he used it on 15 days for a total of 28 times.

    3. In July, he used it on four days for a total of nine times.

    4. In August, he used it on 10 days for a total of 17 times.

    5. In September, he used it on seven days for a total of 14 times.

    6. In October, he used it one time on one day.

    7. There were no records on the Claimant's use of the RS 4i Stimulator for November and December 2003 and January 2004.

    8. In February, he used the device two times on one day.

    9. In the first three weeks of March 2004, he used it on 10 days for a total of 24 times.

9. The Claimant's use of the RS 4i Stimulator, as shown by the records described in Finding of Fact No. 8, is at variance with his testimony at the hearing that he has used the device every day.

10. The Claimant said he used a TENS unit before using the RS 4i Stimulator and the TENS unit also provided relief, although not as much as the RS 4i Stimulator.

11. A TENS unit is not efficacious for providing chronic pain relief.

12. The Claimant experienced a placebo effect from the use of the TENS unit and from the RS 4i Stimulator.

13. The RS 4i Stimulator is not shown to be reasonably required by the nature of the Claimant's injury.

14. All parties received not less than ten 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.

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

III. CONCLUSIONS OF LAW

1. 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(k) and TEX. GOV'T. CODE ANN. ch. 2003.

2. Petitioner timely requested a hearing in this matter pursuant to 28 TEX. ADMIN. CODE (TAC) '§§ 102.7 and 148.3.

3. Notice of the hearing was proper and complied with the requirements of TEX. GOV'T. CODE ANN. ch. 2001.

4. RS Medical has the burden of proof in this matter, which was the preponderance of evidence standard. 28 TAC §148.21(h); 1 TAC § 155.41(b).

5. The only issue in this proceeding is whether the device is reasonable and medically necessary for the Claimant as of the date of the hearing. 28 TAC § 134.600.

6. RS Medical did not prove the RS 4i Stimulator is medically necessary for the Claimant. TEX. LAB. CODE ANN. § 408.021(a).

7. Association Casualty should not have to provide the RS 4i Stimulator to the Claimant.

ORDER

IT IS THEREFORE ORDERED that RS Medical's request for relief is **DENIED** and Association Casualty Insurance Company is not ordered to provide the RS Medical RS-4i Sequential Stimulator for the Claimant.

SIGNED May 5, 2004.

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