SOAH DOCKET NO. 453-04-1189.M2
TWCC MR No. M2-04-0075-01

RS MEDICAL,	§	**BEFORE THE STATE OFFICE**
Petitioner	§	
	§	
V.	§	
	§	**OF**
SERVICE LLOYDS 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 authorizes the purchase of the RS 4i Stimulator.

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 Service Lloyds Insurance Company (Service Lloyds). Susan Keesee, RS Medical's Insurance Relations Manager, and Claimant testified for RS Medical. Leonard Hershkowitz, M.D., testified for Service Lloyds. 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 sustained a work-related injury to her lower back on or about _____, while descending the stairs at her place of employment during a bomb scare. She was treated with

chiropractic care, physical therapy, LESI, oral medications, and an IDET procedure.[1] She has had pain in her lumbar spine since her injury. In May 2003, her doctor, Aaron Calodney, M.D., prescribed the RS 4i Stimulator for two months to relieve and manage chronic pain, relax muscle spasms, and prevent and retard disuse atrophy. In July 2003, Dr. Calodney prescribed the device for an indefinite period for the same purposes. On his prescription, he indicated it provided improved muscle conditioning and pain relief.

The United States Food and Drug Administration (FDA) has cleared the RS 4i Stimulator to relieve acute pain and relieve and manage chronic pain.[2] The FDA said, The RS-4i family is substantially equivalent to its legally marketed predecessor the RS-4M+ (K000114) muscle stimulator.[3]

Service Lloyds 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.[4]

Employees are entitled to necessary health care 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

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1 The IDET procedure and LESI were not defined in the record and the ALJ was unable to determine their meaning from medical dictionaries.

2 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.

3 *Id.* at 4.

4 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.

health care includes all reasonable and necessary medical . . . services.

As Appellant, RS Medical had the burden of proof.[5]

B. Testimony and Contentions

1. RS Medical

Dr. Calodney wrote in a letter dated July 28, 2003,[6] accompanying his prescription of the RS 4i Stimulator for indefinite use that the Claimant reported a decrease in pain of approximately 50 percent and decreased muscle spasms. He said she was able to use the device rather than additional oral medications during times of increased pain. In another letter written on the same date,[7] Dr. Calodney said the Claimant had recently undergone a lumbar IDET procedure. He said he has had great success using RS 4i Stimulator as post-operative therapy for patients who have had the procedure. He said the device causes a reduction and in some cases elimination of disuse atrophy that plagues patients who undergo IDET procedures. He said the Claimant has reported an ability to engage in increased activity through the use of the device.

In a March 16, 2004, response to RS Medical,[8] Dr. Calodney 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 her to use the device. He does not believe that patients achieve benefits from the device only in the acute phase following an injury.

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5 1 TEX. ADMIN. CODE (TAC) § 155.41; 28 TAC § 148(h).

6 Ex. 2 at 2.

7 *Id.* at 3.

8Ex. 9.

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.[9] 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 resistence and allows much deeper penetration. This distinguishes it from a TENS unit, which is a low-frequency device that meets significant skin resistence. 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 Service Lloyd's experts, reviewed TENS devices, but 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 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 she uses the RS 4i Stimulator an average of three to five times a day, including each night to help her sleep. The more active she is, the more she needs to use it. Her husband is a pastor and she uses it more on Sundays. She often uses it before and after an activity. She has used it more in recent weeks since Service Lloyds has discontinued its approval of anti-inflammatory medications. She said she still experiences a lot of pain even with medications and the use of the device. She said at present it looks like she will need back surgery.

RS Medical introduced testimonials from several sports teams extolling the use of the RS 4i Stimulator.[10] Many said they used the device for chronic pain relief as well in the acute phase

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

10 Ex. 6-9.

following an injury.[11]

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. Service Lloyds

Leonard Hershkowitz. M.D., a board certified neurologist, testified on behalf of Service Lloyds. He said the interferntial current is like two TENS units set to interfere with one another. He acknowledged that the unit Ais said to give a deeper penetration than a TENS unit alone. He indicated the device 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 her 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 using the device, or medication reductions. He would regard as significant, for example, documentation that drug use was cut in half by using the device. He referred to this as evidence-based medicine, and cited it as the standard for determining medical necessity.

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

11 Ex. 7 at 5, 7, and 8; Ex. 8.

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 he said the RS 4i Stimulator is similar to a TENS unit, which was discussed in the report. He has not seen any studies or other evidence to recommend electrical stimulation after the acute phase.

The IRO doctor said a muscle stimulator can be useful as adjunctive therapy in the acute phase of treatment, but not after. The doctor said this view is the standard of care and is supported by findings in the Philadelphia study.[12]

Peer reviews provided to Service Lloyds said passive modalities like the RS 4i Stimulator are recognized in the acute phase of an injury, but not in the chronic phase. An orthopedic surgeon and a pain management and rehabilitation specialist provided the reviews. One of the doctors cited the Philadelphia study as finding little or no evidence supporting the use of electrical stimulators for longer than six weeks post-injury.[13]

In another peer review, concerning various aspects of the Claimant's treatment, an orthopedic surgeon concluded that the clinical documentation he reviewed did not support ongoing care for the Claimant, including the RS 4i Stimulator.[14]

Service Lloyds said it did not discount subjective reports from the Claimant, but argued there is insufficient objective medical documentation in this case to conclude that the device is medically necessary. It argued that no one knows the condition the Claimant would be in without the device.

C. Analysis

12 Ex. 10 at 3.

13 Ex. 10 at 11-14.

14 Ex. 10. At 16.

The ALJ concludes that the RS 4i Stimulator was shown to be reasonably required by the nature of the Claimant's injury for pain relief as of the date of the hearing. This conclusion is based primarily on the Claimant's believable and persuasive testimony that the device greatly relieves her pain. She uses it several times a day and was specific about its helping her at night, before and after church, and following other activities. Although her testimony was subjective only, her doctor did say it has helped reduce her dependence on medications.[15] She said she has needed to use the RS 4i Stimulator more often since Service Lloyds has discontinued approval of another pain relieving treatment, anti-inflammatories, which she said had helped her. With the help of the device, she is trying to avoid using Vicodin.

Although there is insufficient objective evidence to satisfy Dr. Herschkowitz's standard for finding medical necessity, the ALJ nonetheless concludes that the Claimant's strong testimony on how the device has reduced her pain and helped her through daily living activities, combined with Dr. Calodney's statement that it helps to reduce pain and drug intake, carries more weight.

Although Service Lloyd's evidence concerning the lack of efficacy of electrical stimulators in general after the acute phase of an injury carried some weight, it did not specifically focus on interferential devices. Dr. Herschkowitz acknowledged that interferential devices are said to provide greater pain relief.

The Claimant proved that the purchase of the RS 4i Stimulator on a rent-to-own basis was medically necessary.[16] The device is approved on that basis or until the Claimant has surgery, whichever occurs first.

II. FINDINGS OF FACT

15 The Claimant's doctor also provided medical-expert-opinion testimony that the RS Stimulator was medically necessary.

16 Under a rent-to-own arrangement, the insurance carrier pays monthly rentals to RS Medical until the purchase price is paid or until the patient stops using the device.

1. The Claimant sustained a work-related injury to her lower back on or about _____, while descending the stairs at her place of employment during a bomb scare.

2. The Claimant was treated with chiropractic care, physical therapy, LESI, oral medications, and an IDET procedure.

3. The claimant has had pain in her lumbar back area since her injury.

4. In May 2003, the Claimant's doctor, Aaron Calodney, M.D., prescribed the RS 4i Sequential Stimulator (RS 4i Stimulator) for two months to relieve and manage chronic pain, relax muscle spasms, and prevent and retard disuse atrophy.

5. In July 2003, Dr. Calodney prescribed the device for an indefinite period.

6. Service Lloyds denied the claim and an independent review organization (IRO) upheld the denial.

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

8. The United States Food and Drug Administration (FDA) has cleared the RS 4i Stimulator to relieve acute pain and relieve and manage chronic pain.

9. The FDA said, The RS-4i family is substantially equivalent to its legally marketed predecessor the RS-4M+ (K000114) muscle stimulator.

10. Service Lloyds did not contest the efficacy of the RS 4i Stimulator for use during the acute phase of an injury.

11. The Claimant uses the RS 4i Stimulator an average of three to five times a day, including each night to help her sleep.

12. The more active the claimant is, the more she needs to use the RS 4i Stimulator, including using it more before and after church, where her husband is the pastor.

13. The Claimant has used the RS 4i Stimulator more in recent weeks since Service Lloyds has discontinued its approval of anti-inflammatories, which was another treatment that helped relieve her pain.

14. The Claimant still experiences a lot of pain even with medications and the use of the RS 4i Stimulator.

15. The Claimant may undergo back surgery.

16. The Claimant has had a decrease in pain of approximately 50 percent and decreased muscle

spasms as a result of using the RS 4i Stimulator.

17. After undergoing a lumbar IDET procedure, the RS 4i Stimulator helped reduce the Claimant's pain.

18. The Claimant has an ability to engage in increased activity through the use of the RS 4i Stimulator.

19. With the help of the RS 4i Stimulator, the Claimant is trying to avoid using Vicodin.

20. The RS 4i Stimulator is reasonably required by the nature of the Claimant's injury.

21. 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.

22. 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. RS Medical 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. 28 TAC § 148.21(h); 1 TAC § 155.41(b).

5. The only issue in this proceeding is whether the RS 4i Stimulator is reasonable and medically necessary for the Claimant as of the date of the hearing. 28 TAC § 134.600.

6. The purchase of the RS 4i Stimulator on a rent-to-own basis is medically necessary. TEX. LAB. CODE ANN. § 408.021(a).

7. Service Lloyds should provide the RS 4i Stimulator to the Claimant on a rent-to-own basis, or until the Claimant has low back surgery for her pain, whichever occurs first.

ORDER

THEREFORE IT IS ORDERED that RS Medical's request for relief is **GRANTED** and the RS Medical RS-4i Sequential Stimulator is authorized on a rent-to-own basis for the Claimant or until she has surgery for her low-back pain, whichever occurs first.

SIGNED May 7, 2004.

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