SOAH DOCKET NO. 453-04-1176M2R

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

DECISION AND ORDER

RS Medical requested a hearing to contest an Independent Review Organization (IRO) decision denying preauthorization of a RS 4i Sequential Stimulator (RS 4i Stimulator) for indefinite use by an injured worker (Claimant). The Administrative Law Judge (ALJ) concludes the RS 4i Stimulator was shown to be medically necessary.

A hearing convened on May 4, 2004, before ALJ James W. Norman at the State Office of Administrative Hearings, Austin, Texas. Patrick K. Cougill represented RS Medical. Tommy W. Lueders represented American Motorists Insurance Company (American Motorists). Susan Keesee, RS Medical's Insurance Relations Manager, and Claimant testified for RS Medical. Leonard Hershkowitz, M.D., testified for American Motorists.[1] There were no contested issues of notice or jurisdiction. The record closed on May 18, 2004, with the submission of additional documentation.

I. DISCUSSION

A. Background

The Claimant, a ___ year old female at the time, sustained a work-related-cervical-spine injury on ___, in a car accident while delivering medications to nursing homes. She has not been able to work since, although she has tried without success to hold part-time jobs. Her diagnosis is neck pain and radiculopathy. She has had extensive treatment modalities consisting of medications, epidural steroid injections, aqua therapy, physical therapy, biofeedback, and a pain program. She has had depression, anxiety, and other personal problem issues. She said she received a TENS unit in 1996 that helped, but at another point said it aggravated her condition. She first began using the RS 4i Stimulator in May of 2003.

The Claimant received maximum-medical-improvement ratings in 1995 of seven percent and ten percent. An independent medical evaluation in 2000 concluded that no further treatment was indicated and recommended that she return to work immediately at medium-duty level.

The Claimant's treating physician, Howard Kweller, M.D., prescribed the RS 4i Stimulator for two months on May 8, 2003, and then for indefinite use on July 17, 2003. American Motorists denied the indefinite-use request for preauthorization and the IRO concluded on October 14, 2003, that the purchase should be denied.

[1] RS Medical adopted Ms. Keesee=s testimony from appeals by RS in Docket Nos. 453-04-1018.M2 and 453-04-1189.M2. American Motorists adopted Dr. Herschkowitz=s testimony from the same dockets.

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]

American Motorists 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 have a right to necessary health treatment under TEX. LABOR CODE ANN. '' 408.021 and 401.011. Section 408.021(a) provides, AAn 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 Aall reasonable and necessary medical . . . services.@

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

B. Testimony and Contentions

1. RS Medical

Dr. Kweller wrote the following in a letter dated July 7, 2003:[6]

> ___. . . has been using the RS-4i Stimulator with excellent results in decreasing pain and muscle spasms, as well as improving overall muscle condition.
>
> The RS 4i Stimulator is indicated for relieving acute pain, and relieving or managing chronic pain, relaxation of muscle spasms, prevention or retardation of disuse atrophy, maintaining or increasing range of motion, and enhancing local blood circulation.
>
> ___. . . is able to use this therapy at home, thereby reducing costs related to outpatient

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[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.

[5] 1 TEX. ADMIN. CODE (TAC) ' 155.41; 28 TAC ' 148(h).

[6] Ex. 2 at 4.

> physical therapy. The RS 4i Stimulator provides a non-invasive, non-narcotic alternative to drugs. . . .
>
> I have found the RS 4i Stimulator to be very cost effective. It enhances the healing process significantly. The RS 4i Stimulator is not a T.E.N.S. unit and many patients are able to effectively control their pain through its use.

The Claimant testified and submitted a letter supporting her need for the RS 4i Stimulator. She said it has helped Atremendously@ in relieving pain, which is often Asevere,@ and in reducing her need for drugs, including pain and muscle spasm medications. She has not used a TENS unit since receiving the device. She said the RS 4i Stimulator penetrates deeply into her muscles compared to the TENS unit, which aggravates her condition.[7] She maintained it is helpful for her neck, shoulder, shoulder blades, lower back, and mid-back. She indicated she uses it throughout the week and sometimes daily. It permits her to engage in activities she might otherwise be unable to do.

The Claimant said she discusses the device and its benefits with Dr. Kweller when she sees him although she now sees him only every two to three months because American Motorists has stopped paying for the visits. Dr. Kweller refills her prescriptions when she sees him.

The Claimant also said American Motorists has Acut way down@ on paying for her drugs, including pain medications. She maintained the RS 4i Stimulator has helped to reduce her medication needs. She believes her condition would be much worse without the device and she would need more pain medications.

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.[8] 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 APhiladelphia Panel Physical Therapy Study@ (Philadelphia study), cited by American Motorists= experts and the IRO doctor, reviewed TENS, not interferential, devices.

Ms. Kessee cited a study by Anthony Yeung entitled, AEffect 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.

There is extensive evidence showing the Claimant's use of the RS 4i Stimulator. In

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[7] She also said the TENS unit made a Atremendous difference@ when she got it in 1996.

[8] Ms. Kessee was not shown to be a medical expert.

May 2003, she used it a total of 36 times over 21 days.[9] In June 2003, she used it a total of 32 times over 22 days.[10] In July 2003, she used it a total of 22 times over 10 days.[11] In August 2003, she used it a total of 15 times over seven days.[12] In September 2003, she used it a total of 32 times over 14 days.[13] In October 2003, she used it a total of 31 times over 15 days.[14] In November 2003, she used it a total of 41 times over 15 days.[15] In December 2003, she used it a total of 16 times over six days.[16] In January 2004, she used it a total of 26 times over 10 days.[17] In February 2004, she used it a total of nine times over four days.[18] In March 2004, she used it a total of five times over four days.[19] April 2004, she used it a total of nine times over six days.[20]

RS Medical introduced testimonials from several sports teams extolling the use of the RS 4i Stimulator.[21] Many said they used the device for chronic pain relief as well as in the acute phase following an injury.[22]

RS Medical contended the RS 4i Stimulator has reduced the Claimant's pain and dependence on drugs and has permitted her to engage in activities she could not otherwise do. It argued the Philadelphia Study applies to TENS units, not the RS 4i Stimulator. It cited Commission newsletters (in relation to a American Motorists contention that the Claimant's use of the device was not for her compensable injury), which said that insurers should decide whether to preauthorize a treatment on the basis of medical necessity only rather than deciding contestability issues.

2. American Motorists

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[9] Ex. 2 at 8.

[10] Ex. 8 at 22.

[11] Ex. 8 at 20.

[12] Ex. 8 at 18.

[13] Ex. 8 at 16.

[14] Ex. 8 at 14.

[15] Ex. 8 at 12.

[16] Ex. 8 at 10.

[17] Ex. 8 at 8.

[18] Ex. 8 at 6.

[19] Ex. 8 at 4.

[20] Ex. 8 at 2.

[21] Ex. 7.

[22] Ex. 7 at 3, 6, and 9.

Dr. Herschkowitz testified that the interferntial current is like two TENS units set to interfere with one another. He acknowledged that the RS 4i Stimulator 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 several years after an 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 referred to this as Aevidence-based medicine,@ and cited it as the medical standard for determining medical necessity.

Dr. Herskowitz referred to the Philadelphia Study, which concluded that 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. He has not seen any studies or other evidence to recommend electrical stimulation after the acute phase.

The IRO doctor[23] said the standard of care is that the RS 4i Stimulator is accepted as adjunctive therapy in the acute phase of an injury, but that no peer review, double-blind studies show the efficacy of a muscle stimulator in the chronic phase. The doctor said there is no independently confirmable medical evidence demonstrating the RS 4i Stimulator=s usefulness. The doctor cited the Philadelphia Study as supporting this point of view and maintained there are no studies showing that muscle stimulators help increase function or decrease medication use or other types of therapy.

A peer review provided to American Motorists on July 25, 2003,[24] recommended denying the request for preauthorization. It said there is no documentation demonstrating the efficacy of the RS 4i Stimulator. There was no significant muscle spasm or atrophy noted, and the Claimant still has incapacitating pain using the same pain medication. A July 31, 2003, peer review[25] recommended a denial on the same basis.

American Motorists argued there is no evidence the RS 4i Stimulator is useful for chronic pain relief 10 years post-injury. It contended there is no documentation showing a reduction in the Claimant's medication from using the device and no functional capacity evaluation demonstrating increased capacity. It argued that if drugs have been reduced, it is because of its actions, not the Claimant's. It cited the Claimant's testimony that she uses the RS 4i Stimulator for low-back as well as cervical painBit pointed out the Claimant's low-back pain is not part of her compensable injury and argued this factor is important in showing the device is medically unnecessary.

[23] Ex. 9 at 1-4. The IRO doctor is board certified in family practice.

[24] Ex. 9 at 5.

[25] Ex. 9 at 6.

C. Analysis

The ALJ concludes that the RS 4i Stimulator was proved to be medically necessary. The Claimant is not using the device as much in recent months as she was earlier, but she still uses it a significant amount of the time. Her testimony was convincing that it has alleviated her pain and helped reduce her dependance on drugs. Although the weight of evidence from medical experts indicted the device is not useful in the chronic phase of an injury, the FDA has approved it for that use and her treating doctor prescribed it for that purpose. With conflicting evidence on the device=s usefulness for chronic pain, the Claimant's testimony that the device relieves her pain and has reduced her need for medications carried significant weight. American Motorists= argument that her use of the device for a non-compensable purpose shows a lack of medical necessity was not persuasive because she is clearly using it for pain caused by her compensable cervical-spine injury. Overall, there is sufficient evidence to prove the Claimant's present need for the RS 4i Stimulator.

II. FINDINGS OF FACT

1. The Claimant, a ___ year old female at the time, sustained a work-related-cervical-spine injury on ___, in a car accident while delivering medications to nursing homes.

2. The Claimant has not been able to work since her accident, although she has tried without success to hold part-time jobs.

3. The Claimant's diagnosis is neck pain and radiculopathy.

4. The Claimant has had extensive treatment modalities consisting of medications, epidural steroid injections, aqua therapy, physical therapy, biofeedback, and a pain program.

5. The Claimant first began using the RS 4i Stimulator in May of 2003.

6. The Claimant's treating physician, Howard Kweller, M.D., prescribed the RS 4i Stimulator for two months on May 8, 2003, and then for indefinite use on July 17, 2003.

7. American Motorists denied the indefinite-use request for preauthorization.

8. The IRO concluded on October 14, 2003, that the indefinite-use request should be denied.

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

10. 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.

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

12. The United States Food and Drug Administration has cleared the RS 4i Stimulator to, among

other uses, relieve acute pain and relieve and manage chronic pain.

13. The Claimant uses the RS 4i Stimulator a significant amount of the time.

14. The Claimant's use of the RS 4i Stimulator has alleviated her pain and helped reduce her dependance on drugs.

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

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 in this matter, which is 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 RS 4i Stimulator is reasonable and medically necessary for the Claimant as of the date of the hearing. 28 TAC ' 134.600.

6. RS Medical proved the RS 4i Stimulator is medically necessary for the Claimant as of the date of the hearing. TEX. LAB. CODE ANN. ' 408.021(a).

7. American Motorists should provide the RS 4i Stimulator to the Claimant.

ORDER

IT IS THEREFORE ORDERED that RS Medical=s request that the RS 4i Sequential Stimulator be preauthorized for use by the Claimant, be and the same is hereby, approved, and that American Motorists shall provide the RS 4i Sequential Stimulator for indefinite use by the Claimant.

SIGNED June 8, 2004.

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