SOAH DOCKET NO. 453-04-3681.M2
TWCC MR NO. M2-04-0604-01

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

DECISION AND ORDER

I. DISCUSSION

On February 11, 2004, RS Medical (Petitioner) requested a hearing before the State Office of Administrative Hearings (SOAH) following a February 3, 2004 Decision of the Texas Workers' Compensation Commission (Commission) acting through the Texas Medical Foundation, an Independent Review Organization (IRO), denying the preauthorization request of Petitioner for the purchase of an interferential and muscle stimulator for indefinite use by ___ (Claimant).[1]

This decision denies the relief sought by Petitioner.

The hearing on the merits, originally scheduled for April 21, 2004, was continued on the motion of Petitioner and, at the request of Petitioner and Facility Insurance Company (Respondent or Carrier), reset for October 14, 2004. At the parties' request, the case was joined with SOAH Docket No. 453-04-0357.M2 for hearing and reset for the requested date of October 12, 2004. A hearing convened on October 12, 2004, before Administrative Law Judge (ALJ) Howard S. Seitzman. Patrick K. Cougill represented Petitioner. Steve Tipton represented Carrier. The hearing recessed and reconvened on the following dates: October 13, 2004; and October 29, 2004. The record remained open for the filing of additional evidence and briefs. The final briefs were received on March 11, 2005. The record closed on March 14, 2005.

Claimant sustained a work-related injury to her right shoulder on or about ___.On July 25, 2002, Alan D. Kaye, M.D., of the Texas Tech University Health Sciences Center School of Medicine International Pain Institute, prescribed an RS Medical RS-4i interferential and muscle

[1] The decision by the IRO is deemed to be a Commission Decision and Order.

stimulator for a two-month period to treat pain, muscle spasms and atrophy. On October 7, 2003, Dr. Kaye prescribed the RS Medical RS-4i interferential and muscle stimulator for indefinite use.

The RS Medical RS-4i interferential and muscle stimulator is a class II medical device that the United States Food and Drug Administration (FDA) has determined is safe and effective for specified indications.[2] The Carrier's agent, Forté, did not deny preauthorization for the purchase of the RS-4i because the general efficacy of the device for some or all of the specified indications was unproven. On October 17, 2003, Carrier denied preauthorization because the paperwork submitted did not objectively document the benefits to Claimant from the use of the RS-4i.[3] On October 30, 2003, after reviewing additional information from Dr. Kaye, Carrier denied reconsideration because no change in daily pain medication or activities of daily living (ADLs) are noted from the Claimant's 30-day trial period.[4] In both decisions, Carrier identified the source of the screening criteria used as guidelines in making the determination during the review as "Medical Director."[5] Carrier never denied the preauthorization for purchase of the RS-4i on the basis of general efficacy of the device. In fact, Carrier admitted through Forté that " [l]ong-term use of stimulators is appropriate when there has been at least a two month trial to determine effectiveness in significantly increasing ROM,[6] decreasing the use of pain medication, increasing activities, and a decrease in the need of for other use of medical services and other interventional modalities."[7]

[2] "Interferential therapy systems are regulated by the FDA as Class II devices. Over 50 different instruments have received FDA approval." Carrier Ex. 7, p. 45. Although Carrier objected to the ALJ referring to the medical device as FDA approved, the ALJ would note Carrier's own evidence, in addition to the foregoing, identifies a Dynatron model and states it "received FDA approval on May 15, 2001, for symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain." Carrier Ex. 7, p. 45.

[3] Petitioner Ex. 1-4.

[4] Petitioner Ex. 1-7.

[5] Petitioner Ex. 1-4; Petitioner Ex. 1-5.

[6] Range of motion.

[7] Petitioner Ex. 1-6.

Therefore, the ALJ finds that the general efficacy of the device is not an issue so long as the device is prescribed and used for the FDA specified indications.[8] Dr. Kaye prescribed the RS Medical RS-4i for FDA specified indications. Therefore, the only issue in this proceeding is whether the device is reasonable and medically necessary for Claimant as of the date of the hearing.[9]

On or about___, Claimant sustained a work-related injury to her right shoulder. In May 2001 Claimant underwent an arthroscopic procedure to repair a rotator cuff. Claimant also underwent a craniotomy procedure in 2001 and had a chronic cerebrospinal fluid leak. As indicated in the January 21, 2003 treatment notes, Claimant experienced pain on the right side of her back extending through her right leg. For the right back and leg pain, Claimant was prescribed medications and right sided cluneal nerve blocks. As documented in Claimant's October 29, 2003 treatment notes, Claimant continued to experience moderate to severe pain from her right cluneal neuropathy even with the medications and nerve blocks.

As noted in the following discussion, there is evidence in the record that Claimant experiences pain from the work-related rotator cuff injury. There is also evidence in the record of significant pain and disability from medical problems with her hip and low back. As evidenced by her medical reports, Claimant's principal cause of pain and debilitation is not her right shoulder,[10] but her cluneal nerves, hip and spine.[11] There is no evidence that the hip and low back injuries are work-related. The RS-4i was prescribed for the shoulder only. The evidence with respect to the effectiveness of medications prescribed to treat the work-related shoulder injury is inconsistent. In this case, Petitioner's failure to show the medications are ineffective does not militate in favor of medical necessity for the RS-4i.

[8] In support of their legal arguments, both parties filed affidavits from experts as to the meaning of the FDA action regarding the RS-4i.

[9] The ALJ adopts the reasoning of ALJ Norman that the issue of medical necessity relates to present need, as of the date of the hearing, and not past need, as of the date of the prescription. SOAH Docket No. 453-03-4229.M2, MDR No. M2-03-1308-01; *RS Medical v. City of El Paso* (January 6, 2004).

[10] Petitioner Ex. 2-3, 2-4, 2-6, and 2-8.

[11] Petitioner Ex. 2-6.

There is an absence of medical records prior to 2003. The earliest medical records, from January 21, 2003, March 6, 2003, and March 25, 2003, do not refer to right shoulder pain or muscle spasm, but do reference a right rotator cuff arthroscopic repair with good results.[12] Although Lidoderm patches are prescribed on May 5, 2003, there is still no reference to chronic shoulder pain. The first mention of right shoulder pain is in the May 21, 2003 treatment notes when Claimant remarks that she is happy with her Lidoderm patches and requests more for her shoulder.[13] Thereafter, the treatment notes of June 4, 2003, and July 15, 2003, reflect that Claimant experienced chronic pain in her right shoulder from the rotator cuff injury. The treatment notes of September 11, 2003, indicate Claimant is doing well with the RS-4i. Dr. Kaye's progress note of September 15, 2003, indicates Claimant is experiencing decreased pain and muscle spasm with the use of the RS-4i. The October 29, 2003 treatment notes reflect a benefit from Claimant's use of the RS-4i.

The RS-4i contains an onboard data collection system. Usage data for the trial period of July 25, 2003 through September 30, 2003, shows that Claimant used the RS-4i for at least one treatment on 54 of the 68 days, or 79.41% of the possible days.[14]

On October 7, 2003, based upon the results of the trial period, Dr. Kaye prescribed the RS-4i for indefinite use. Usage data for October 7, 2003 through October 31, 2003, shows Claimant used the RS-4i on 18 of the 25 calendar days, or 72% of the days available. For the period March 2, 2004, through September 19, 2004, 201days, Claimant used the device at least once on 153 days, or 76% of the calendar days.

Claimant testified: (1) she used the RS-4i on a daily basis and that the RS-4i treatments reduced her pain; (2) the device assists Claimant in participating in the personal activities of daily living (ADL) and provides relief from muscle spasms; and (3) medications did not relieve her muscle spasms. Claimant testified she uses Bextra daily, a nonsteroidal anti-inflammatory drug; Prevacid daily, which decreases the amount of acid produced in the stomach; Lidoderm patches, in which the lidocaine provides an analgesic effect; and xylocaine, which also contains lidocaine. The

[12] Petitioner Exs. 2-1, 2-2, 2-3 and 2-4.

[13] Petitioner Ex. 2-6.

[14] If one includes the six days in October prior to the prescription for purchase, the Claimant used the device at least once on 60 of the 72 calendar days, or 83% of the available days.

patches are applied to her shoulder for 12 hours during the day and the xylocaine is applied to her shoulder at night.

The RS-4i was prescribed for Claimant's right shoulder. Claimant testified she uses the RS-4i for her shoulder, hip and lower back. Again, there is no evidence the hip and low back injuries are work-related injuries. The RS-4i does not record the anatomical location of the treatment. Thus, the usage data, while impressive, cannot establish or verify the frequency of use of the RS-4i on the right shoulder.

Claimant was prescribed Norflex for muscle spasms and on January 21, 2003, she reported to her treating physician that the Norflex was effective.[15] She started on Lidoderm[16] patches on May 5, 2003,[17] and 16 days later initially reported satisfactory results for her shoulder.[18] On June 4, 2003, Claimant reported the Lidoderm patches helped during the early part of the day but the effect diminished during the afternoon.[19] Claimant requested EMLA cream[20] because it had helped her in the past.[21] Because the pharmacy no longer carried EMLA cream, a combination of Ketamine 1% and Ketoprofen 10% was prescribed for her left shoulder.[22] On July 15, 2003, Claimant reported the patches and Bextra were helping with her pain and the prescription for the Ketamin cream and Bextra were refilled.[23] It appears from the evidence in the record that the medications were effective in treating Claimant's shoulder pain and muscle spasm. Further, it is unclear which ADLs were impeded by the right shoulder injury, as opposed to the hip and low back problems. The ALJ is, therefore, unable to determine with which ADLs the RS-4i assisted Claimant.

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[15] Petitioner Ex. 2-1.

[16] Although Claimant reported to her physician on March 6, 2003, that she had an allergic reaction to Lidocaine, the treating physician questioned her statement. Petitioner Ex. 2-2.

[17] Petitioner Ex. 2-4.

[18] Petitioner Ex. 2-6.

[19] Petitioner Ex. 2-8.

[20] A combination of lidocaine and prilocaine applied topically for analgesic relief.

[21] Petitioner Ex. 2-8.

[22] Petitioner Ex. 2-8. The medical report states "left shoulder." The ALJ assumes the prescription was for her right shoulder because the same medical report indicates chronic right shoulder pain.

[23] Petitioner Ex. 2-9.

Petitioner had the burden of proof in this proceeding. The evidence failed to establish the ineffectiveness of the prescribed medications. The evidence failed to establish which ADLs were impeded by the shoulder injury. The evidence failed to establish consistent usage of the RS-4i on the right shoulder. Overall, Petitioner failed to prove by a preponderance of the evidence that the purchase of an RS Medical RS-4i interferential and muscle stimulator for indefinite use by Claimant is reasonable and medically necessary as of the date of the hearing.

II. FINDINGS OF FACT

1. ___ (Claimant) sustained a work-related injury to her right shoulder on or about___.

2. In May 2001 Claimant underwent an arthroscopic procedure to repair a rotator cuff.

3. Claimant also underwent a craniotomy procedure in 2001 and had a chronic cerebrospinal fluid leak.

4. Claimant experienced pain on the right side of her back extending through her right leg. For the right back and leg pain, Claimant was prescribed medications and right sided cluneal nerve blocks. Even with the medications and nerve blocks, Claimant continued to experience moderate to severe pain from her right cluneal neuropathy.

5. On July 25, 2002, Alan D. Kaye, M.D., of the Texas Tech University Health Sciences Center School of Medicine International Pain Institute, prescribed an RS Medical RS-4i interferential and muscle stimulator for a two-month period to treat pain, muscle spasms and atrophy.

6. On October 7, 2003, Dr. Kaye prescribed the RS Medical RS-4i interferential and muscle stimulator for indefinite use.

7. The RS-4i was prescribed for the shoulder only. The hip and low back injuries are not work-related injuries.

8. Claimant experiences pain and muscle spasms in her right shoulder as a result of her work-related injury.

9. The RS Medical RS-4i interferential and muscle stimulator is a class II medical device approved by the United States Food and Drug Administration (FDA) for specified indications.

10. The RS Medical RS-4i was prescribed for FDA-approved indications.

11. Claimant uses the RS-4i almost every day but consistent use for the right shoulder was not demonstrated.

12. Claimant's right shoulder is not the principal cause of her pain.

13. Petitioner failed to establish that the medications prescribed for Claimant's right shoulder pain and muscle spasm are not effective in treating the conditions.

14. Petitioner failed to establish that the Claimant's right shoulder pain materially inhibits Claimant's activities of daily living.

15. Petitioner failed to establish which activities of daily living are improved by RS-4i treatments of the right shoulder.

16. Facility Insurance Company (Carrier or Respondent) denied Claimant's preauthorization request for purchase of an RS Medical RS-4i as not medically necessary.

17. RS Medical (Petitioner) seeks preauthorization for Claimant's purchase of an RS Medical RS-4i for indefinite use by Claimant.

18. By letter dated February 3, 2004, the Texas Medical Foundation, an Independent Review Organization (IRO), denied the preauthorization request of Petitioner for the purchase of an RS Medical RS-4i for indefinite use by Claimant.

19. The IRO decision is deemed a Decision and Order of the Texas Workers' Compensation Commission (Commission).

20. On February 11, 2004, Petitioner requested a hearing to contest the Commission's decision.

21. By letter dated March 15, 2004, the Commission issued a notice of hearing.

22. The notice contained a statement of the time, place, and nature of the hearing; a statement of the legal authority and jurisdiction under which the hearing was to be held; a reference to the particular sections of the statutes and rules involved; and a short, plain statement of the matters asserted.

23. The hearing on the merits, originally scheduled for April 21, 2004, was continued on the motion of Petitioner and, at the request of Petitioner and Facility Insurance Company (Respondent or Carrier), reset for October 14, 2004. At the parties' request, the case was joined with SOAH Docket No. 453-04-0357.M2 for hearing and reset for the requested date of October 12, 2004.

24. A hearing convened on October 12, 2004, before Administrative Law Judge (ALJ) Howard S. Seitzman. Patrick K. Cougill represented Petitioner. Steve Tipton represented Carrier. The hearing recessed and reconvened on the following dates: October 13, 2004; and October 29, 2004. The record closed on March 14, 2005, after the filing of additional evidence and briefs.

III. CONCLUSIONS OF LAW

1. The Texas Workers' Compensation Commission has jurisdiction to decide the issue presented pursuant to the Texas Workers' Compensation Act, TEX. LAB. CODE ANN. §§ 413.031.

2. 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.

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

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

5. 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).

6. Petitioner had the burden of proof in this matter, which was the preponderance of evidence standard. 28 TAC §§ 148.21(h) and (i); 1 TAC § 155.41(b).

7. Petitioner failed to prove by a preponderance of the evidence that the purchase of an RS Medical RS-4i interferential and muscle stimulator for indefinite use by Claimant is medically necessary.

ORDER

THEREFORE IT IS ORDERED that Petitioner RS Medical's request for relief is **DENIED** and the preauthorization of the purchase of an RS Medical RS-4i interferential and muscle stimulator for indefinite use by___ is **DENIED**.

SIGNED May 17, 2006.

HOWARD S. SEITZMAN
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS