

INSURANCE COMPANY OF THE
STATE OF PA,
Petitioner

§
§
§
§
§
§
§
§
§

BEFORE THE STATE OFFICE

VS.

OF

STAT 2000 AND C.W.,
Respondents

ADMINISTRATIVE HEARINGS

DECISION AND ORDER

The Insurance Company of the State of PA (Carrier) appealed the decision by an Independent Review Organization (IRO) to grant preauthorization for Claimant to purchase a BMR NT 2000 Neuromuscular Stimulator. The cost of the unit is \$2,195.00, plus \$85.00 per month for supplies. Carrier disputes the IRO's conclusion that these services are medically reasonable and necessary. This decision agrees with Carrier and finds that the device is not medically reasonable or necessary for Claimant. Therefore, Carrier's appeal is granted and the decision of the IRO is reversed and set aside.

I. JURISDICTION & HEARING

There were no challenges to notice or jurisdiction, and those matters are set forth in the findings of fact and conclusions of law without further discussion here.

Administrative Law Judge (ALJ) Thomas H. Walston conducted a hearing in this case on August 18, 2003, at the State Office of Administrative Hearings (SOAH), William P. Clements State Office Building, Austin, Texas. Attorney Steve Tipton appeared on behalf of Carrier. Mr. Randy Burgett appeared by telephone on behalf of STAT 2000. The hearing concluded and the record closed the same day.

II. DISCUSSION

1. Background

Claimant is a 50-year-old male who was injured on, when he was rear-ended in a car accident during the course of his employment as a delivery driver for Vitalink Pharmacy Services of San Antonio. Initially received conservative treatment but eventually underwent a lumbar hemilaminectomy at L4-5 bilaterally, along with a fusion and ray cages at that level. The following is a summary of the medical records contained in the IRO file:

- May 27, 1997 - Dr. Joe Gonzales (M.D.) diagnosed condition as lumbosacral strain. He noted that range of motion was reduced about 50% in all directions and that had central canal stenosis at L-1 to L-5.
- October 30, 1997 - Follow-up examination by Dr. Arnulfo Carrasco (M.D.) of the Texas Pain Institute in San Antonio complained of low back pain although he thought it was improving had developed a blood clot in his right leg and had been placed on Coumadin by another doctor. Apparently Dr. Carrasco had previously given injections to relieve pain but decided

to discontinue them due to the blood clot problem. On physical exam, reported minimal tenderness in the low back and right thigh.

- January 20, 1998- Follow-up visit to Dr. Carrasco. complained of chronic pain in his low back and legs. He was undergoing physical therapy at the time and thought he was improving. On physical examination walked with a normal gait and without difficulty. He reported some tenderness in the low back, but his lumbar range of motion had improved. Dr. Carrasco prescribed Darvocet, told to continue physical therapy, and scheduled a follow-up visit in four months.
- March 3, 1998 - Dr. Gonzales assessed with a 13% whole person impairment rating. He noted that continued to have low back pain, that he had received two epidural steroid injections, and that was working with the Texas Rehabilitation Commission for job placement continued to complain of low back pain, particularly with prolonged sitting, standing, or stooping. Dr. Gonzales reported that had sustained a lumbosacral contusion, that he was neurologically and orthopedically stable, and that he had reached maximum medical improvement as of March 3, 1998.
- June 9, 1998 - Dr. Carrasco reported that was essentially normal except for chronic low back pain that was worse with prolonged sitting. He noted that had returned to work and recommended continued conservative care.
- June 30, 1998 - Dr. Jose Santos, (M.D.) issued a designated doctor evaluation report. Dr. Santos summarized the medical conditions noted above, including the severe spinal stenosis at L4-5. The physical examination was generally normal except for limited range of motion. Dr. Santos agreed that reached MMI on March 3, 1998, and he assessed with an 11% whole person impairment.
- December 12, 1998 - A lumbar myelogram report from Dr. Nadi Hibri (M.D.) stated that had significant narrowing of the spinal canal at L4-5, apparently due to spinal stenosis, but an associated disk herniation could not be ruled out. He also noted mild narrowing of the rest of the lumbar spinal canal. A post-myelogram CT scan showed the severe stenosis at L4-5 was secondary to bulging of the disk margin, but there was no evidence of disk herniation.
- February 18, 1999 - Dr. Gonzales met with for a pre-surgical evaluation continued to complain of low back pain and had reduced range of lumbar motion in all directions.
- August 12, 1999 - Follow-up visit to Dr. Roberto J. Aranibar (M.D.) had completed phase one of physical therapy and seemed to be improving. Dr. Aranibar noted that weighed 327 pounds and was having some pain in his right knee. The physical examination was normal. The doctor instructed to resume phase two of his physical therapy [3 X per week for 4 weeks] and renewed a prescription for Lortab.
- September 1, 1999 - Letter from Dr. Santos stating that he would increase impairment rating from 11% to 14% due to surgery. This report states that underwent a lumbar hemilaminectomy at L4-5 bilaterally, along with a fusion and ray cages at that level. Dr. Santos also noted that reached statutory MMI on February 6, 1999.
- September 23, 1999 - Report from Dr. Aranibar indicates that was essentially unchanged from August 12, 1999.

- February 28, 2000 - Dr. Santos issued another impairment rating at the request of TWCC. Physical examination showed good muscle strength in the lower extremities but decreased reflexes and neurological function. Due to decreased range of motion, Dr. Santos raised rating to a 27% whole person impairment, compared to a previous 14% rating.
- February 13, April 13, July 18, and October 10, 2001 - handwritten notes from Dr. Gonzales for these dates are somewhat difficult to read. Apparently, continued to complain of chronic low back pain and had somewhat limited lumbar range of motion. Range of motion was normal in the cervical spine and the exams were otherwise unremarkable. Dr. Gonzales continued to prescribe various medications.
- January 8, 2002 - handwritten note by Dr. Gonzales indicates that was working and doing well, although he complained of chronic spinal pain gait was normal, and he had good range of motion and a normal neurological examination. Dr. Gonzales renewed prescriptions for Celebrex and Lortab.
- April 2, 2002 - handwritten notes by Dr. Gonzales state that was working but was not able to exercise regularly. He thought had poor conditioning complained that his job made it hard to work out at a gym, so Dr. Gonzales prescribed a treadmill and told to continue his medications.
- July 1, 2002 - Report of a follow-up office visit with Dr. Gonzales. reported that he was doing fairly well, with frequent episodes of muscular pain in his neck and low back. On this visit asked Dr. Gonzales about obtaining a neuromuscular stimulator for self application as a method of pain relief. Dr. Gonzales discussed other options, but stated that he wanted to try a stimulator. exam was essentially normal except for complaints of discomfort in the neck. However, Dr. Gonzales prescribed a neuromuscular stimulator for
- August 30, 2002 - letter on Dr. Gonzales' letterhead to the Carrier's adjuster. This letter states that on July 17, 2002, was fitted with a neuromuscular stimulator device by a clinician with STAT 2000. It also states that complained of unbearable pain at a level of 8 on a scale of 1-10 and that he had developed disuse atrophy due to his lack of activity. It added that reported a reduction of pain and that he had a good prognosis with the device but a poor prognosis without it. As will be discussed later, Carrier questions whether Dr. Gonzales actually authored this letter.

On September 13, 2002, STAT 2000 requested preauthorization for to purchase a BMR NT 2000 Neuromuscular Stimulator. STAT 2000 quoted a purchase price of \$2,195.00 plus \$85.00 per month for supplies. On September 18, 2002, GENEX Services denied the request on behalf of Carrier based on lack of medical necessity. STAT 2000 requested reconsideration of the decision, but on October 3, 2002, Carrier again denied preauthorization. The denial noted that had reported subjective improvement in his pain with use of the device in the short term, but it also stated that there was no evidence that the device was effective in reducing pain with long term use.

STAT 2000 appealed to the IRO, Envoy Medical Systems. The IRO granted STAT 2000's appeal and ordered Carrier to preauthorize the neuromuscular stimulator. The IRO stated its rationale as follows:

Although studies have not shown that the stimulator units are beneficial, individual patients can achieve significant improvement that warrants use of the stimulator unit. This patient has achieved documented, marked benefit from the stimulator unit.

This appeal by Carrier followed.

B. Medical Necessity of the BMR NT2000 Neuromuscular Stimulator

1. Carrier's Evidence and Arguments

Carrier argues that a neuromuscular stimulator is not designed to reduce pain. Instead, its purpose is to stimulate nerves and muscles to prevent muscle wasting and atrophy in cases of stroke or other muscle immobilization. Because did not have any condition or problem that a neuromuscular stimulator is designed to treat, Carrier argues that it was not medically reasonable or necessary for ___ treatment and care.

Carrier called Dr. Leonard Hershkowitz as a witness. Dr. Hershkowitz has been a board certified neurologist since 1976. In addition to maintaining an office practice, he teaches at the Baylor College of Medicine and the University of Texas Medical Branch at Houston. His specialty involves injuries and diseases related to nerves and muscles, and he is knowledgeable about physical therapy modalities for injuries and strokes.

Dr. Hershkowitz stated that neuromuscular stimulators have been around for several years and can be useful for some orthopedic and neurological conditions. He explained that a neuromuscular stimulator stimulates a muscle with an electrical charge so the muscle will contract. These are usually used on muscles that do not contract or function due to nerve damage. Thus, the stimulator bypasses the nerve, causes the muscle to contract, and avoids muscle atrophy due to lack of use. Typically, Dr. Hershkowitz stated, neuromuscular stimulators are used for patients with muscle weakness due to stroke or nerve-root problems that prevent a muscle from being stimulated naturally. They can also be used in orthopedic cases where a muscle cannot be flexed due to an immobilizing cast. As noted, a neuromuscular stimulator is used to avoid atrophy due to disuse of a muscle.

Dr. Hershkowitz reviewed medical records, but he has not examined Based on the records, he stated that does not show any type of nerve injury, muscle weakness, or other problem that would benefit from the use of a neuromuscular stimulator. Dr. Hershkowitz noted that injury occurred in, that had back surgery with a fusion, and that he currently has failed-back syndrome and chronic back pain. But, in Dr. Hershkowitz' opinion, these conditions do not support the use of a neuromuscular stimulator. He agreed that in some cases a stimulator might be useful in the acute or subacute phases shortly after surgery when a patient cannot use certain muscles due to pain, but he stated that stimulators generally are not used to treat chronic pain. In short, Dr. Hershkowitz testified that a neuromuscular stimulator is a good device, but it simply is not used to treat chronic pain and it is not medically reasonable or necessary to treat

Dr. Hershkowitz also questioned whether received any benefit from temporary use of the device, as stated by the IRO, or whether he simply received a placebo effect. He pointed out that Dr. Gonzales' report dated July 1, 2002, stated that *requested* a stimulator. The report states that Dr. Gonzales discussed other options, but insisted on obtaining a stimulator. As a result, Dr. Gonzales prescribed the neuromuscular stimulator even though exam on that date was essentially normal except for unquantified minor pain. Although reported some reduction in pain, Dr. Hershkowitz testified that this was likely a temporary placebo effect, which is more likely to occur when a patient asks for a particular treatment and then receives it. In addition, Dr. Hershkowitz pointed out that a neuromuscular stimulator is not designed to relax muscles or reduce pain. In fact, Dr. Hershkowitz stated, a stimulator is designed to perform the opposite function of stimulating and contracting muscles, not relaxing them.

Finally, Dr. Hershkowitz had some doubt about whether Dr. Gonzales actually authored the August 30, 2002, letter contained in the IRO file, that referred to as having “muscle spasticity” and disuse atrophy.” Those conditions occur with neurological conditions such as cerebral palsy or stroke, but not with a low back injury such as Carrier’s counsel also pointed out that the letter has a different font than Dr. Gonzales’ other letters, and the language in the letter sounds more like product marketing than a medical report. Also, when the Carrier contacted Dr. Gonzales on September 16, 2002 (while the request for preauthorization was pending), Dr. Gonzales stated that he had not seen since July 1, 2002, which contradicts statements in the August letter.

On cross examination, Dr. Hershkowitz stated that he was not familiar with the specific model prescribed for He was aware of a 1997 article that suggests a TENS-neuromuscular stimulator combination unit may provide greater pain relief than either alone, but he stated that it was a poor, if not completely invalid, study, because it used only 24 patients, relied on entirely subjective patient reports, and tested the patients over a period of only two days. Dr. Hershkowitz also does not dispute that has chronic pain. He sees patients with chronic pain and agrees that treatment sometimes does not relieve the pain. Likewise, he does not believe that the neuromuscular stimulator involved in this case will relieve chronic pain.

Carrier also called Mr. Randy Burgett of STAT 2000 as an adverse witness. Mr. Burgett testified that he did not know who prepared the letter with Dr. Gonzales’ signature dated August 30, 2002. However, he did state that employees of STAT 2000 frequently assist doctors in drafting letters to request preauthorization so that the letters will meet the requirements of TWCC’s rules. He also testified that a STAT 2000 Registered Nurse named Glenda Kight fitted with the neuromuscular stimulator in question.

In argument, Carrier states that the IRO ordered preauthorization based solely on initial, subjective statement that he received some pain relief from the stimulator. Carrier also argues that the August 30, 2002, letter on Dr. Gonzales’ letterhead was likely written by someone at STAT 2000 and stamped with Dr. Gonzales’ signature. The letter is printed with a different font than the doctor’s other reports, it appears to have a stamped signature, it contradicts Dr. Gonzales’ progress notes, and Dr. Gonzales reported to the carrier on September 16, 2002, that he had not seen since July 1. In summary, based on Dr. Hershkowitz’ testimony and medical records, Carrier argues that a neuromuscular stimulator is not medically reasonable and necessary for and should not be preauthorized.

2. STAT 2000's Evidence and Arguments

STAT 2000 did not call any witnesses at the hearing, but it did introduce documentary evidence into the record. These include an FDA-approved Form 501(k) Premarket Notification concerning the BMR NT2000 Neuromuscular Stimulator and several IRO decisions that authorized use of the device. STAT 2000 complains that Dr. Hershkowitz is not familiar with this specific device and argues that his opinions should be discounted. STAT 2000 also argues that Dr. Gonzales’ letter dated August 30, 2002, is genuine and that reduced pain while temporarily using the device establishes that it should be preauthorized.

3. ALJ's Analysis and Decision

The ALJ concludes that the BMR NT2000 Neuromuscular Stimulator is not medically reasonable or necessary for the treatment of Dr. Hershkowitz' testimony was clear that the purpose of a neuromuscular stimulator is to stimulate muscles to prevent muscular atrophy rather than to relax muscles or reduce pain. In this case, however, did not have muscle wasting due to lack of use, which is the condition the stimulator is designed to address. Instead, Dr. Gonzales prescribed the device, at the request of to treat chronic pain.

As the ALJ understands the evidence, a TENS (Transcutaneous Electrical Nerve Stimulation) unit is a different device than a neuromuscular stimulator, and the two devices are used for different purposes. Thus, the Form 501(k) introduced into evidence by STAT 2000 states that the TENS unit is used to treat chronic intractable pain, while the neuromuscular stimulator is used to prevent disuse muscular atrophy. This is consistent with and supports Dr. Hershkowitz' testimony. But in this case, the medical records are clear that does not have disuse muscular atrophy, for which a neuromuscular stimulator device would be appropriate. Instead, he only had complaints of chronic pain.

STAT 2000 points out that the unit in question includes both a TENS unit and a neuromuscular stimulator, and it argues that one published study found that such a combination unit may provide better relief to some patients than either of the units provide separately. However, the study was not introduced into evidence, and Dr. Hershkowitz disputed the validity of the study due to its small size and study techniques. Based on the limited evidence in the record, the ALJ agrees with Dr. Hershkowitz that the study is of dubious value. Further, even if the study were valid, it would not, by itself, establish that a combination unit would provide with more relief than a less expensive TENS unit.

Under the workers' compensation system, an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury. The employee is specifically entitled to health care that: (1) cures or relieves the effects naturally resulting from the injury; (2) promotes recovery; or (3) enhances the ability to return to or retain employment. TEX. LABOR CODE ANN. § 408.021. "Health care" includes "all reasonable and necessary medical . . . services" and "medical appliances." TEX. LABOR CODE § 401.011(19)(F). However, the statute also requires that treatment shall be cost effective. *See* TEX. LABOR CODE § 413.011(g). In this case, providing with a combination TENS unit-neuromuscular stimulator would not be as cost effective as providing a less expensive, simple TENS unit.

In this case, Carrier has proven by a preponderance of the evidence that a neuromuscular stimulator is not medically reasonable or necessary for the treatment of because a neuromuscular stimulator is designed to treat muscular disuse atrophy-which does not have- rather than pain, which does have. Although STAT 2000 contends that a combination TENS unit-neuromuscular stimulator such as the unit in question can provide pain relief, the ALJ finds that such a unit is not the least intensive, most cost-effective device available to treat pain. Therefore, the ALJ grants Carrier's appeal and finds that preauthorization for a BMR NT2000 Neuromuscular Stimulator should be denied.

III. FINDINGS OF FACT

1. Claimant suffered a compensable injury on, when he was rear-ended in a car accident during the course of his employment for ____.
2. Received conservative treatment, as well as surgery in February 1999 that included a lumbar hemi-laminectomy with fusion at L4-5 bilaterally. Dr. Joe Gonzales, M.D., is primary treating physician.
3. On July 1, 2002, at request, Dr. Gonzales prescribed a neuromuscular stimulator for self-application as a method of pain relief and requested preauthorization for the prescription.
4. The Insurance Company of the State of PA, the Carrier, denied Dr. Gonzales' request.
5. STAT 2000, the supplier of the neuromuscular stimulator, requested medical dispute resolution.
6. The Independent Review Organization (IRO) granted STAT 2000's request for preauthorization.
7. Carrier requested a contested case hearing before the State Office of Administrative Hearings and requested denial of preauthorization for the neuromuscular stimulator.
8. A neuromuscular stimulator is designed to treat muscular disuse atrophy, not pain.
9. Does not have muscular disuse atrophy.
10. A neuromuscular stimulator is not medically reasonable or necessary for the treatment of pain resulting from compensable injury.
11. ALJ Thomas H. Walston conducted a hearing in this case on August 18, 2003.
12. The Carrier and STAT 2000 attended the hearing.
13. 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; a reference to the particular sections of the statutes and rules involved; and a short, plain statement of the matters asserted.
14. All parties were allowed to respond and present evidence and argument on each issue involved in the case.

IV. CONCLUSIONS OF LAW

1. The State Office of Administrative Hearings has jurisdiction over matters related to the hearing, including the authority to issue a decision and order. TEX. LABOR CODE ANN. § 413.031(k).

2. All parties received proper and timely notice of the hearing. TEX. GOV'T CODE ANN. §§ 2001.051 and 2001.052.
3. Carrier has the burden of proof by a preponderance of the evidence. 28 TEX. ADMIN. CODE § 148.21(h) and (i).
4. Carrier proved by a preponderance of the evidence that a neuromuscular stimulator is not medically reasonable or necessary for the proper treatment of TEX. LABOR CODE ANN. §§ 401.011(19) and 408.021.
5. Carrier's appeal is granted and Carrier is not required to pay for a neuromuscular stimulator for as requested by Dr. Joe Gonzales, M.D.

ORDER

IT IS, THEREFORE, ORDERED that preauthorization is hereby DENIED for a BMR NT2000 Neuromuscular Stimulator for as requested by STAT 2000 and Dr. Joe Gonzales, M.D.

SIGNED September 15, 2003.

STATE OFFICE OF ADMINISTRATIVE HEARINGS

THOMAS H. WALSTON
ADMINISTRATIVE LAW JUDGE