

March 29, 2004

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TWCC Medical Dispute Resolution
MS-48
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MDR Tracking #: M2-04-0946-01
IRO #: 5251

___ has been certified by the Texas Department of Insurance as an Independent Review Organization. The Texas Worker's Compensation Commission has assigned this case to ___ for independent review in accordance with TWCC Rule 133.308 which allows for medical dispute resolution by an IRO.

___ has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed.

The independent review was performed by a matched peer with the treating doctor. This case was reviewed by a licensed Medical Doctor board certified and specialized in Orthopedic Surgery. The reviewer is on the TWCC Approved Doctor List (ADL). The ___ health care professional has signed a certification statement stating that no known conflicts of interest exist between the reviewer and any of the treating doctors or providers or any of the doctors or providers who reviewed the case for a determination prior to the referral to ___ for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

CLINICAL HISTORY

The claimant is a 46 year old right-handed Master mechanic who injured his shoulder on ___ while removing an air compressor with his arms in an overhead position. He did not have a pop, but started having discomforted and noted bruising throughout his shoulder. He underwent conservative care along with injections, physical therapy and work hardening. It appears from the history that the claimant had prior surgery of the shoulder, nevertheless he had done fairly well with his rehab effort and returned back to a different job that did not require as much overhead work. An RS4 Muscle Stimulator Unit was initiated for treatment around the end of July 2003 and was reported to keep the symptoms under control.

The issue at hand is the necessity of a purchase of an RS4i Medical Device for indefinite use. In the preauthorization process this was denied for a variety of reasons.

One rationale reported that this device is not broadly accepted as a pervading standard of care and is not recommended as medically necessary; passive modalities are indicated in the acute phase of care, and the use must be time limited. The Philadelphia Panel Physical Therapy study found little or no supporting evidence to include such modalities in treatment of chronic pain greater than six weeks. A response letter regarding Medical Dispute Resolution filed by the DME Company, RS Medical was submitted on 3/5/04 from an attorney's office, which reviewed a previous SOAH decision. In review of the SOAH decision it appears to be an issue regarding reimbursement rate and in the statement of facts there is no evidence that the RS4 device was a unique product or anything other than a muscle stimulator.

Included are 'critically appraised papers' from PT Global Net regarding these issues. An article 'Pulse Ultrasound and Interferential Therapy Do Not Reduce Shoulder Pain or Disability' is an article that pulse ultrasound does reduce shoulder pain and disability due to calcific tendonitis.

A medical policy statement 5.01.01 regarding interferential current stimulation opined that the use of interferential current stimulation for treatment of pain, decreased range of motion and wound healing was considered investigational and not medically necessary.

Another article from the Archives of Physical Medicine and Rehabilitation 1999 obtained from Medscape opined that interferential current did not produce an effect different from those produced than with a TENS unit and that the TENS unit clearly was more effective than interferential in developing wave lengths felt to be the most efficacious.

Articles from the Regents Group and Blue Cross Blue Shield policy reviews defined interferential as the crossing of two medium independent frequencies working together to stimulate a large impulse fiber to interfere with transmission of pain messages at the spinal cord level. A muscle electrical stimulator device stimulates the motor nerves and alternatively causes contractions and relaxation of muscles to prevent and retard disuse atrophy and to relax muscle spasms and increase blood circulation and maintain range of motion and re-educate the muscles.

The recapitulation suggested that both interferential and neuromuscular electrical stimulator devices were considered investigational procedure for use in the home setting. The rationale was that treatment for pain with these devices was highly susceptible to placebo effect and there were not good studies using sham devices in review of the literature for long term studies.

There are letters of recommendation from ___ regarding the necessity for an RS4 Stimulator and the fact that it relieved the spasms and increased range of motion and function for this shoulder pain it was going to be required for indefinite use.

Included are the 'Smart Card' readings revealing the utilization of the device, both in frequency and duration and it appears that in the months of October, November, and December, the claimant used the muscle stimulator intermittently throughout the month, but did not use the interferential at all. Further review reveals that the request for rental of this device was approved for two months, based on the studies presented for perusal where muscle stimulators were used for two months. This article is typically submitted in conjunction with RS4i Medical requests and is authored by John Glaser at the Department of Orthopaedic Surgery at the University of Iowa. It is a study with electrical muscle stimulator only and the device was used for only two months; there was no use of interferential reported in this study. This study does not reveal use of this device long term.

REQUESTED SERVICE

The purchase of an RS-4i interferential and muscle stimulator is requested for this patient.

DECISION

The reviewer agrees with the prior adverse determination.

BASIS FOR THE DECISION

In review of the medical records on this claimant, the decisions regarding previous scrutiny, and current literature, and utilization of this particular device it is recommended to uphold the preauthorization review decision in denying purchase for indefinite use of the RS4i Medical Device combination interferential/neuromuscular stimulator for treatment of intermittent discomfort of the shoulder sprain/strain previously operated.

The rationale for this decision is based on the information submitted, in addition to evidenced based medicine published by the Cochran's Collaboration and the Philadelphia Panel. The use of a TENS unit is an anecdotal response and cost effective if appropriate in dealing with pain. The use of a muscle stimulator to help treat muscle injuries is appropriate for acute and sub-acute injuries, but it is unclear the efficacy of this device for chronic long-term use as suggested by the literature. Whereas electrical devices were not found effective for shoulder pain, ultrasound was found effective for pain due to calcific tendonitis. In this case it appears that the claimant has discovered that the interferential unit of the RS4i Medical Device was ineffective since it was placed more appendicular than axial (it is designed more for axial placement). In fact, over the past three months, according to the Smart Card data, only the muscle stimulator unit was used. Although the SOAH decision stated that the RS4i Medical Device was not unique and was nothing more than a muscle stimulator it is unclear the medical necessity to purchase a combination device for the added expense when a device including a muscle stimulator only would be considered much more cost effective. The only studies submitted by RS4i Medical in support of their device for use in Texas Worker's Compensation is the Iowa study where the muscle stimulator was used for two months only, then study for efficacy for a few months afterward.

A long-term study using placebos, sham and double-blinded review of the combination device in comparison of other devices would be helpful to confirm medical necessity of a purchase.

To recapitulate, this request is to purchase an RS4i Medical Device combination unit of interferential and muscle stimulator in a claimant with shoulder pain. In the past three months of utilization, the claimant was only using the muscle stimulator component, and therefore it does not appear medically necessary to purchase a device that has a combination unit.

___ has performed an independent review solely to determine the medical necessity of the health services that are the subject of the review. ___ has made no determinations regarding benefits available under the injured employee's policy.

As an officer of ___, I certify that there is no known conflict between the reviewer, ___ and/or any officer/employee of the IRO with any person or entity that is a party to the dispute.

___ is forwarding by mail and, in the case of time sensitive matters by facsimile, a copy of this finding to the treating doctor, payor and/or URA, patient and the TWCC.

Sincerely,

YOUR RIGHT TO REQUEST A HEARING

Either party to medical dispute may disagree with all or part of the decision and has a right to request a hearing.

If disputing a spinal surgery prospective decision, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **10 (ten)** calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

If disputing other prospective medical necessity (preauthorization) decisions, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **20 (twenty)** calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

This decision is deemed received by you 5 (five) days after it was mailed or the date of fax (28 Tex. Admin. Code 102.5(d)). A request for a hearing and a **copy of this decision** must be sent to:

Chief Clerk of Proceedings / Appeals Clerk
P.O. Box 17787
Austin, Texas 78744
Fax: 512-804-4011

The party appealing this decision shall deliver a copy of its written request for a hearing to other party involved in this dispute.

I hereby certify, in accordance with TWCC Rule 102.4 (h), that a copy of this Independent Review Organization decision was sent to the carrier, requestor, claimant (and/or the claimant's representative) and the TWCC via facsimile, U.S. Postal Service or both on this 29th day of March 2004.