

July 12, 2004

MDR Tracking #: M2-04-1449-01
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 patient is approximately 52 years of age. He has had a chronic low back condition since 1983. He has had a total of three operations, the last of which was performed under a Worker's Compensation claim and he has never returned back to work since the surgery was performed. He has had a host of treatment including surgery, post-operative therapy, chronic pain management, injections, medication and time. In the fall of 2003 he was started on an RS4 Medical Device as a rental unit. The prescription stated that physical therapy, hot packs and medication had been tried. The prescription did not reveal that he had had surgery on his back. A voluminous amount of records were submitted regarding this patient's care, and it appears some of which was submitted by the DME company, the majority of which was provided by the treating physicians offices. It includes clinic notes from ___, ___, and treating psychologist during the pain management program. Superbill charges were also submitted and range from daily office visits to the single level decompression arthrodesis performed.

This patient is currently being managed with off work status with medication that includes a Duragesic patch that was cascaded from 50 to 100 mcgs every two days. He is also taking Flexeril, Restoril, Neurontin, Lexapro and Viagra.

It appears that the medication has cascaded in doses during the time that the RS4 medical device has been used. There is no report of increased activities or decreased medication as a result of this device. There are multiple entries of letters and/or prescriptions for this device that are unsigned. There is even one note where handwritten overwrite on a letter suggested that the doctor would not sign it until he saw the patient.

Absent from these records is whether the purchased device would be discounted by the rental to date, but present are references to the 'smart card,' a service provided by RS4 Medical regarding utilization of this equipment both in duration and frequency. The request for this device was turned down twice by peer reviewing physicians for ____.

Included in the records are references to a previous SOAH hearing where the RS4 Medical device was not determined to be unique to justify a higher charge. Also submitted were a variety of position statements by third party institutions such as Blue Cross Blue Shield regarding the use of electrical devices for chronic pain in an arena that is highly placebo and anecdotal. One of the studies that RS4 Medical usually submits in their claims for purchase and/or rental is an Iowa study where the device was used for two months and then the population was followed for six months thereafter, suggesting some efficacy in the short term and beyond the use of the equipment, however there was a high drop out rate and it is unclear to be scientifically sound in regard to efficacy and the conclusion of that article was that further studies were needed.

REQUESTED SERVICE

An RS4i medical device is requested for this patient.

DECISION

The reviewer agrees with the prior adverse determination.

BASIS FOR THE DECISION

Evidenced based medicine, particularly the information published by the Philadelphia Panel does not support the use of these devices in managing chronic pain. Criteria often adhered to by a peer reviewing physician and/or physician advisors for utilization review in the preauthorization process for Worker's Compensation in Texas include cost effective management, obvious increased activity, reduction of medication, return to work status, etc. There are modalities that are much more cost effective such as a TENS unit, interferential unit, or a muscle stimulator unit; in which there are no documentation that these units have been tried. An RS4i Medical device typically charges \$2495.00 for a purchase, with a variety of charges for set up and one-time fees. They have previously advertised that any rental price would be discounted from the purchase price, although there is no mention of this in the records submitted for this perusal. Smart card information was submitted with this claim and shows that this patient used this on a daily or every other day basis, sometimes five times longer than originally prescribed. ____ reported that he should use this device up to two times a day for up to 40 minutes at a time, yet the smart card information showed that the patient used this device for four hours at a time. Also interesting in the smart card information is that the interferential device was never used, it was all muscle stimulation, which in effect negates the indication for this specific brand, which is advertised as a dual device, using both interferential and muscle stimulation. The letters submitted were sometimes signed, sometimes not signed, and suggest that this device was necessary to retard muscle atrophy, increase mobility, promote healing and restoration of return to work, etc. This patient is several years beyond this level of recovery and the literature supports that if an injured worker has not gone back to work in two years that it is highly unlikely that he will return back to work. This statement has been reinforced by examining or peer reviewing physicians in this case, such as ____, a professor of spine surgery at ____.

The carrier has invested significant sums of money in regard to the treatment and recovery of this injured worker without success. The surgery, the chronic pain management, the medication, the physical therapy, all have resulted in the injured worker not returning back to work, suggesting that all treatments to date have been unsuccessful for this chronic back condition, exacerbated/aggravated at work. The criteria commonly used in the preauthorization process for rental and purchase this device specifically did not employ the dual purpose, has not resulted in decreased medication use or increased activities and trial of other devices have not been documented to show that one particular device is more effective than another.

Since the documentation on utilization of this device under rental shows that only the muscle stimulator was used, it does not appear necessary to purchase this device for additional functions not being used.

Critical information in regard to purchase of this device for this patient was not made available in the amount discounted due to rental to date, which is assumed to be a greater amount than the funds required to file this IRO review. If the anecdotal experience is that a muscle stimulator does give him some relief and the interferential component is not being employed, it is not medically necessary from a medical (or economic) standpoint for this device to only being used as a muscle stimulator. This is typically a short term, acute management process for muscle injuries. The mechanism of this device designed to treat is the interferential component, which is not being used. Perhaps the prescribing physician may scrutinize the choice of products, although ___ and ___ have both signed letters and prescriptions for this device, it is unclear if either physician is in support of this IRO appeal submitted by the DME company itself.

___ 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 12th day of July, 2004.