

**THIS DECISION HAS BEEN APPEALED. THE FOLLOWING
IS THE RELATED SOAH DECISION NUMBER:
SOAH DOCKET NO. 453-04-1317.M2**

NOTICE OF INDEPENDENT REVIEW DETERMINATION

MDR Tracking Number: M2-04-0237-01
IRO Certificate Number: 5259

October 30, 2003

An independent review of the above-referenced case has been completed by a medical physician board certified in physical medicine and rehabilitation. The appropriateness of setting and medical necessity of proposed or rendered services is determined by the application of medical screening criteria published by Texas Medical Foundation, or by the application of medical screening criteria and protocols formally established by practicing physicians. All available clinical information, the medical necessity guidelines and the special circumstances of said case was considered in making the determination.

The independent review determination and reasons for the determination, including the clinical basis for the determination, is as follows:

See Attached Physician Determination

___ hereby certifies that the reviewing physician is on Texas Workers' Compensation Commission Approved Doctor List (ADL). Additionally, said physician has certified that no known conflicts of interest exist between him and any of the treating physicians or providers or any of the physicians or providers who reviewed the case for determination prior to referral to ___.

Sincerely,

CLINICAL HISTORY

This gentleman sustained a lumbar spine injury. The initial evaluation and treatment was chiropractic. There was no amelioration of symptoms and referral to an orthopedist was completed. MRI noted a disc lesion. This was treated surgically. There was a repeat herniation and a second surgery was required. There was a DVT and a pulmonary embolus that required anti-coagulation. After using the device requested, there continued to be a need for oral and topical medicines. Oral narcotic use had not declined with the trial use of the device.

According to the patient directed utilization and response chart dated February 23, 2003 there was an increase in muscle spasm, interference with activities and an increase in the need for oral analgesics. Maximum medical

improvement was declared by the Designated Doctor and a 10% whole person impairment rating assigned.

REQUESTED SERVICE(S)

Purchase RS4i Stimulator

DECISION

Endorse pre-authorization determination (deny purchase).

RATIONALE/BASIS FOR DECISION

The primary treating physician failed to produce any competent, objective, and independently confirmable medical evidence demonstrating the efficacy of this device. The utilization curve from December through February documented and there is no measurable improvement in this condition. Has the use of oral analgesic been reduced? There is no data to indicate that is the case. Consequently, there is no established positive result from this use of this device. Moreover, there is no clinical assessment made by the primary treating physician that would support the use let alone the purchase of this device. The progress notes of the provider do not mention the device and the only letters of medical necessity are boilerplate vendor generated documents. Lastly, this is a passive device and noting the date of injury, this claimant should be doing only those active modalities that enhance the rehabilitation of this injury.

The proposed device is not broadly accepted as the prevailing standard of care in the twice surgically treated, fused and instrumented lumbar spine. Such passive modalities are indicated in the acute phase of care and their use must be time-limited. The Philadelphia Panel Physical Therapy Study found little or no supporting evidence to include such modalities in the treatment of chronic pain greater than 6 weeks. Moreover, the efficacy of this type of device in the long-term patient has been studied repeatedly. As noted by Herman (Spine 1994 Mar 1;19(5):561) this treatment adds no apparent benefit. As described by Deyo (NEJM 1990 Jun 7(23):127-34) TENS is no more effective than placebo. The literature of blinded peer-reviewed studies does not support the efficacy of this device. The one study that was completed had a drop out rate of more than 50%, the appropriate methodologies were not reported and the overall efficacy was not a function of the device rather other external factors.

In summary, this device does not improve the clinical situation, there is no identification of a decrease in medication use as a result of this device and the functionality of the claimant was not changed as a result of the device. The pathology is in the disc; the current talked about does not reach the level of the pathology.

YOUR RIGHT TO REQUEST A HEARING

Either party to this 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 (20 Tex. Admin. Code 142.5©).

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 148.3).

This decision is deemed received by you 5 (five) days after it was mailed or the date of fax (28 Tex. Admin. Code 102.4(h) or 102.5(d)). A request for a hearing and a **copy of this decision** must be sent to:

Chief Clerk of Proceedings/Appeals Clerk
Texas Workers' Compensation Commission
P.O. Box 17787
Austin, Texas 78744

Or fax the request to (512) 804-4011. A copy of this decision must be attached to the request.

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

In accordance with Commission Rule 102.4(h), I hereby verify that a copy of this Independent Review Organization (IRO) Decision was sent to the carrier, the requestor and claimant via facsimile or U.S. Postal Service from the office of the IRO on this 3rd day of November 2003.