

June 21, 2005

TEXAS WORKERS COMP. COMISSION
AUSTIN, TX 78744-1609

CLAIMANT: ___
EMPLOYEE: ___
POLICY: M2-05-1844-01
CLIENT TRACKING NUMBER: M2-05-1844-01 /5278

Medical Review Institute of America (MRIOA) has been certified by the Texas Department of Insurance as an Independent Review Organization (IRO). The Texas Workers Compensation Commission has assigned the above mentioned case to MRIOA for independent review in accordance with TWCC Rule 133 which provides for medical dispute resolution by an IRO.

MRIOA 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. Itemization of this information will follow.

The independent review was performed by a peer of the treating provider for this patient. The reviewer in this case is on the TWCC approved doctor list (ADL). The reviewer has signed a statement indicating they have no known conflicts of interest existing between themselves and the treating doctors/providers for the patient in question or any of the doctors/providers who reviewed the case prior to the referral to MRIOA for independent review.

Records Received:

Records Received from the State:

Notification of IRO assignment dated 6/8/05, 6 pages
Notice utilization review findings dated 4/8/05, 2 pages
Notice utilization review findings dated 4/21/05, 2 pages

Records Received from the Requestor:

Statements of medical necessity dated 11/23/04 and 2/7/05, 2 pages
Progress notes dated 1/11/05 and 3/2/05, 2 pages
RS Medical interferential muscle stimulator patient progress note dated 3/7/05, 1 page
Letter from Dr. D'Agostino dated 3/20/05, 1 page

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Clinic note dated 3/20/05, 1 page

Letter from ____ dated 4/27/05, 1 page

RS Medical patient usage reports for dates 11/23/04 through 4/14/05, 12 pages

Fax transmittal form from RS Medical dated 6/14/05, 1 page

Records Received from the Respondent:

Letter from Steven M. Tipton dated 6/15/05, 3 pages

Notice of utilization review findings dated 4/6/05, 2 pages

Notice of utilization review findings dated 4/21/05, 2 pages

Neuromuscular electrical stimulation (NMES) auto denial, dated 2005, 1 page

CMS Medicare coverage database, printed 3/3/04 and 12/14/03, 7 pages

Physical Medicine and Rehabilitation for Orthopedic and Musculoskeletal Disease and/or Injuries, undated, 8 pages

ACOEM guidelines, printed 8/24/04, 2 pages

Initial Approaches to Treatment, Occupational Medicine Practice Guidelines, undated, 12 pages

Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Low Back Pain, dated 10/01, 27 pages

Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Neck Pain, dated 10/01, 17 pages

Interferential therapy: lack of effect upon experimentally induced delayed onset muscle soreness dated 9/1/02, 1 page

An investigation into the analgesic effects of different frequencies of the amplitude-modulated wave of interferential current therapy on cold-induced pain in normal subjects dated 9/1/03, 1 page

Technology, Computing and Simulation dated 10/10/00, 14 pages

Critically Appraised Papers dated 2000, 10 pages

Medical policy on interferential current stimulation dated 8/1/01, 1 page

Alteration of interferential current and transcutaneous electrical nerve stimulation frequency: effects on nerve excitation dated 9/99, 1 page

Durable medical equipment section - electrical stimulation devices dated 1/7/03, 6 pages

Decision and order before the State Office dated 1/3/03, 5 pages

Notice of independent review determination dated 7/29/03, 3 pages

Notice of independent review determination dated 8/20/03, 3 pages

Notice of independent review decision dated 11/5/03, 3 pages

Notice of independent review decision dated 11/17/03, 3 pages

Letter from Independent Review Incorporated dated 11/5/03, 3 pages

Review from ZRC dated 9/29/03, 3 pages

Notice of independent review determination dated 9/18/03, 3 pages

Notice of independent review decision dated 8/7/03, 3 pages

Review from ZRC, undated 3 pages

Notice of independent review determination dated 10/2/03, 3 pages

Review from ZRC dated 8/4/03, 3 pages

Decision and order before the State Office dated 1/3/03, 5 pages

Notice of independent review decision dated 9/23/03, 2 pages

Letter from James R. Sheffield, III dated 5/31/05, 2 pages

Medical dispute resolution request/response, date received from respondent 5/27/05, 3 pages

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Review from ZRC dated 4/15/05, 2 pages

Review from ZRC dated 5/5/05, 1 page

Summary of Treatment/Case History:

The claimant is a 47 year old lady who allegedly suffered a workplace injury on _____. Subsequently she developed neck pain with radiation to the shoulders and the left arm. A trial use of the RS-4i stimulator has apparently been somewhat effective in providing temporary relief of the pain. No further medical information is available.

Questions for Review:

1. Preauthorization denied for purchase of RS-4i sequential, 4 channel combo interferential and muscle stimulator. Please address medical necessity.

Explanation of Findings:

1. Preauthorization denied for purchase of RS-4i sequential, 4 channel combo interferential and muscle stimulator. Please address medical necessity.

Published studies report varying degrees of efficacy for interferential current stimulation (IFCS) in the treatment of chronic pain. Some studies indicate that IFCS is completely ineffective {e.g. Alves-Guerrero (2001); Minder (2002); Taylor (1987); Der Heijden (1999)} and some show it to have an efficacy comparable to that of TENS (transcutaneous electrical nerve stimulation), at best {e.g. Johnson and Tabasam (2003); Palmer, ST (1999)}. A placebo-controlled study of the use of interferential stimulation in postoperative pain {Jarit, 2003} did find some beneficial effect, but this was not compared with TENS treatment. There is some evidence in the published literature of marginal benefit from muscular stimulation {e.g. Glaser (2001)}, but this is not sufficiently clear and significant to warrant the purchase of this expensive unit. The RS-4i interferential/muscular stimulator is an expensive, proprietary device, which offers no apparent advantages over cheaper TENS units, and therefore should not be considered to be medically necessary because of the lack of evidence of specific efficacy for the claimant's chronic pain syndrome. The fact that a device has been granted FDA 510(k) pre-market clearance on the basis of substantial equivalency to an older device, perhaps one marketed prior to the effective date of the law requiring FDA approval, does not imply any official determination that the procedures for which it is employed are standard medical care.

Conclusion/Decision to Not Certify:

Purchase of the RS-4i interferential/muscle stimulator is not medically necessary.

Applicable Clinical of Scientific Criteria or Guidelines Applied in Arriving at Decision:

The Medicare selection criteria for neuromuscular stimulators are:

Coverage of NMES to treat muscle atrophy is limited to the treatment of patients with disuse atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves and other non-neurological reasons for disuse atrophy. Examples include casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins).

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References Used in Support of Decision:

Medicare Coverage Issues Manual, Sec 35-77, Rev. 160. Centers for Medicare and Medicaid Studies.

Defrin, et al. (2005). Segmental noxious versus innocuous electrical stimulation for chronic pain relief and the effect of fading sensation during treatment. *Pain* 115:152-60.

Jarit, et al. (2003). The effects of home interferential therapy on post-operative pain, edema, and range of motion of the knee. *Clin J Sport Med* 13:16-20.

Alves-Guerreiro, et al. (2001). The effect of three electrotherapeutic modalities upon peripheral nerve conduction and mechanical pain threshold. *Clin Physiol* 21:704-11.

Minder, et al. (2002). Interferential therapy: lack of effect upon experimentally induced delayed onset muscle soreness. *Clin Physiol Funct Imaging* 22:339-47.

Taylor, et al. (1987). Effects of interferential current stimulation for treatment of subjects with recurrent jaw pain. *Phys Ther* 67:346-50.

Van Der Heijden, et al. (1999). No effect of bipolar interferential electrotherapy and pulsed ultrasound for soft tissue shoulder disorders: a randomised controlled trial. *Ann Rheum Dis* 58:530-40.

Johnson and Tabasam (2003). An investigation into the analgesic effects of interferential currents and transcutaneous electrical nerve stimulation on experimentally induced ischemic pain in otherwise pain-free volunteers. *Phys Ther* 83:208-23.

Palmer, et al. (1999). Alteration of interferential current and transcutaneous electrical nerve stimulation frequency: effects on nerve excitation. *Arch Phys Med Rehabil* 80:1065-71.

Glaser, et al. (2001). Electrical Muscle Stimulation as an Adjunct to Exercise Therapy in the Treatment of Non Acute Low Back Pain: A Randomized Trial. *The Journal of Pain* 2:295-300.

Moore and Shurman (1997). Combined neuromuscular electrical stimulation and transcutaneous electrical nerve stimulation for treatment of chronic back pain: a double-blind, repeated measures comparison. *Arch Phys Med Rehabil* 78:55-60.

The physician providing this review is board certified in Anesthesiology. The reviewer holds additional certification in Pain Medicine from the American Board of Pain Medicine. The reviewer is a diplomate of the national board of medical examiners. The reviewer has served as a research associate in the department of physics at MIT. The reviewer has received his PhD in Physics from MIT. The reviewer is currently the chief of Anesthesiology at a local hospital and is the co-chairman of Anesthesiology at another area hospital. The reviewer has been in active practice since 1978.

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

YOUR RIGHT TO REQUEST A HEARING

Either party to the medical dispute may disagree with all or part of this 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 receiving the TWCC chief Clerk of Proceedings within ten (10) days of your receipt of this decision as per 28 Texas 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 twenty (20) days of your receipt of this decision as per Texas Admin. Code 102.4 (h) or 102.5 (d). A request for hearing should be sent to:

Chief Clerk of Proceedings
Texas Workers' Compensation Commission
POB 40669
Austin, TX 78704-0012

A copy of this decision should be attached to the request. The party appealing the decision shall deliver a copy of its written request for a hearing to all other parties involved in the dispute

It is the policy of Medical Review Institute of America to keep the names of its reviewing physicians confidential. Accordingly, the identity of the reviewing physician will only be released as required by state or federal regulations. If release of the review to a third party, including an insured and/or provider, is necessary, all applicable state and federal regulations must be followed.

Medical Review Institute of America retains qualified independent physician reviewers and clinical advisors who perform peer case reviews as requested by MRloA clients. These physician reviewers and clinical advisors are independent contractors who are credentialed in accordance with their particular specialties, the standards of the American Accreditation Health Care Commission (URAC), and/or other state and federal regulatory requirements.

The written opinions provided by MRloA represent the opinions of the physician reviewers and clinical advisors who reviewed the case. These case review opinions are provided in good faith, based on the medical records and information submitted to MRloA for review, the published scientific medical literature, and other relevant information such as that available through federal agencies, institutes and professional associations. Medical Review Institute of America assumes no liability for the opinions of its contracted physicians and/or clinician advisors. The health plan, organization or other party authorizing this case review agrees to hold MRloA harmless for any and all claims which may arise as a result of this case review. The health plan, organization or other third party requesting or authorizing

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this review is responsible for policy interpretation and for the final determination made regarding coverage and/or eligibility for this case.

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CC: RS Medical
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