

January 19, 2005

TEXAS WORKERS COMP. COMISSION
AUSTIN, TX 78744-1609

CLAIMANT:

EMPLOYEE:

POLICY: M2-05-0539-01

CLIENT TRACKING NUMBER: M2-05-0539-01/5278

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 12/3/04, 1 page

Letter from TWCC dated 12/30/04, 1 page

Medical dispute resolution request/response, date stamp for receipt from requestor 12/6/04, 4 pages

Notice of utilization review findings dated 10/13/04, 2 pages

Notice of utilization review findings dated 10/27/04, 2 pages

Records Received from the Requestor:

Progress note dated 3/2/04, 1 page

Progress note dated 6/3/04, 1 page

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RS Medical prescription dated 6/18/04, 1 page
RS Medical prescription dated 9/2/04, 1 page
Letter from Dr. Bartel dated 9/13/04, 1 page
Progress note dated 9/23/04, 1 page
Patient health report dated 6/11/04 and 8/17/04, 1 page
Patient usage report dated 6/24/04 through 8/15/04, 6 pages

Records Received from the Insurance Company:

Notice of utilization review findings dated 10/13/04, 2 pages
Letter from Forte dated 10/13/04, 1 page
Notice of utilization review findings dated 10/21/04, 3 pages
Notice of utilization review findings dated 10/27/04, 2 pages
Letter from Forte dated 10/27/04, 1 page
Patient claim notes for dates 3/2/04 through 10/27/04, 3 pages
Preauthorization peer review form dated 1/12/04, 1 page
RS Medical prescription dated 9/2/04, 1 page
Letter of medical necessity dated 9/13/04, 1 page
Letter from RS Medical dated 10/20/04, 2 pages
Request for authorization, undated, 2 pages
Second request for authorization, undated, 1 page
Appeal decision dated 10/26/04, 1 page
Request for authorization dated 10/7/04, 1 page
Notice of intent to issue an adverse determination dated 10/12/04, 1 page
Notice of intent to issue an adverse determination dated 10/12/04, 1 page
Acknowledgement of reconsideration request dated 10/20/04, 2 pages
Acknowledgement of reconsideration request dated 10/20/04, 1 page
Acknowledgement of reconsideration request dated 10/20/04, 1 page
Letter of agreement dated 10/20/04, 1 page
Expanded problem focused history and exam dated 11/15/00, 2 pages
Outpatient followup report dated 1/8/01, 2 pages
Office note dated 2/8/01, 1 page
Outpatient followup report dated 3/8/01, 1 page
Outpatient followup report dated 4/12/01, 1 page
Operative report dated 6/19/01, 1 page
Outpatient followup report dated 6/21/01, 2 pages
Outpatient procedure report dated 7/9/01, 1 page
Outpatient followup report dated 8/7/01, 1 page

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Operative report dated 8/27/01, 1 page
Outpatient followup report dated 9/27/01, 1 page
Office note dated 10/3/01, 1 page
Outpatient followup report dated 11/9/01, 1 page
Outpatient followup report dated 12/6/01, 1 page
Outpatient followup report dated 12/19/01, 1 page
Operative procedure report dated 1/29/02, 2 pages
Outpatient followup report dated 3/7/02, 2 pages
Outpatient followup report dated 3/20/02, 1 page
Outpatient followup report dated 4/17/02, 1 page
Outpatient followup report dated 5/17/02, 2 pages
Outpatient followup report dated 6/13/02, 1 page
SOAP note dated 1/23/03, 1 page
Outpatient followup report dated 8/5/02, 1 page
Outpatient followup report dated 9/12/02, 1 page
Outpatient followup report dated 10/10/02, 1 page
Outpatient followup report dated 11/12/02, 1 page
Outpatient followup report dated 1/6/03, 1 page
Followup progress note dated 1/16/03, 1 page
Outpatient followup report dated 1/21/03, 1 page
Myelogram lumbar report dated 2/7/03, 2 pages
CT lumbar spine report dated 2/7/03, 2 pages
History and physical dated 4/3/03, 2 pages
Operative report dated 5/19/03, 1 page
Followup patient visit dated 10/8/03, 4 pages
Progress note dated 1/04, 1 page
Progress note dated 3/2/04, 1 page
Progress note dated 6/3/04, 1 page
Progress note dated 9/23/04, 1 page
Radiology report dated 3/30/01, 1 page
Radiology report dated 3/30/01, 1 page
Electromyography report dated 4/5/01, 1 page
Price list, effective date 1/01, 1 page
RS-4i Sequential Stimulator information, undated, 1 page
RS-4i Features, undated, 1 page
Article: Electrical Muscle Stimulation as an Adjunct to Exercise Therapy in the Treatment of Nonacute Low Back Pain: A Randomized Trail, accepted date 3/6/01, 6 pages
View claim detail printout dated 10/7/04, 1 page
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Letter of agreement, undated, 1 page
Note printouts dated 9/10/04, 3 pages
Physicians list, undated, 1 page

Summary of Treatment/Case History:

The claimant is a 64 year old female who allegedly suffered a workplace injury on _____. Subsequently she developed pain in her right knee. She proceeded to receive a right total knee replacement several years later. The claimant also suffers from back and right leg pain due to degenerative disc disease. She has undergone at least two lumbar spine operations and is considered to have post-laminectomy syndrome. She has been treated conservatively with multiple medications and injections, including facet joint injections and selective nerve root blocks. None of this has apparently been effective in relieving her pain. Most recently she has been prescribed an RS-4i interferential/muscle stimulator, which she apparently used for 46 days. She reported on 8/17/04 that the stimulation had decreased her pain; however, there is no objective evidence of increased function or decreased use of pain medications.

Questions for Review:

Please address prospective medical necessity of the proposed purchase of an RS-4i sequential four-channel combination interferential and muscle stimulator unit, regarding the above-mentioned injured worker.

Explanation of Findings:

The submitted medical record does not substantiate the efficacy of the RS-4i in terms of increased physical function or decreased use of pain medicine by the claimant. 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 a proprietary device, which offers no apparent advantages over less expensive TENS units, and therefore is not considered medically necessary because of 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.
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Conclusion/Decision to Not Certify:

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

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

In order to be considered to be standard medical care, a new treatment must have been shown to be safe and effective in at least two independent scientifically-valid randomized controlled trials from two unrelated institutions or research groups, or at least one randomized controlled multi-center study that reports data separately from each center. These studies must have been carried out by investigators who are independent of, and not receiving support from, the manufacturer or sponsor of the new treatment and must have been published in the reputable peer-reviewed medical journals which are accepted for indexing in the standard medical bibliographic indices such as Index Medicus.

References Used in Support of Decision:

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 a Acute Low Back Pain: A Randomized Trial. The Journal of Pain 2:295-300.

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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.

MRIoA 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 MRIoA clients. These physician reviewers and (continued)

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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 MRIoA 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 MRIoA 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 MRIoA 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 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: Requestor and Respondent