March 31, 2005

TEXAS WORKERS COMP. COMISSION
AUSTIN, TX 78744-1609

CLAIMANT:
EMPLOYEE:
POLICY: M2-05-1164-01
CLIENT TRACKING NUMBER: M2-05-1164-01 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 3/16/05, 8 pages

RECORDS RECEIVED FROM DR. SWANN:
Neurosurgical Evaluation dated 11/5/02, 2 pages
Review of Lumbar MRI dated 11/20/02, 1 page
Neurosurgical Follow-up dated 7/24/03, 6/1/04, 9/16/04, 3 pages
Review of MRI dated 6/2/04, 1 page
MRI Spine report from Radiology Associates dated 11/19/02, 2 pages

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RECORDS RECEIVED FROM R.S. MEDICAL:
Neurosurgical Follow-up dated 9/16/04, 1 page
Prescription dated 10/7/04, 12/7/04, 2 pages
Letter of Medical Necessity from Karl Swann, MD dated 12/13/04, 2 pages

RECORDS RECEIVED FROM STONE LOUGHLIN & SWANSON LLP:
Letter addressed to MRIoA dated 3/18/05, 8 pages
Letter from Concentra dated 1/6/05, 2 pages
Letter from Concentra dated 1/18/05,
Page with Concentra letter head but no writing date stamped 3/2/05, 1 page
Macro form letter for IRO assignment, no specific patient, dated 10/30/02, 2 pages
State office Administrative Hearings Decision and Order, patient blacked out, undated, 7 pages
Notice of Independent review Determination from Medical Review of Texas, patient blacked out, undated, 4 pages
Notice of Independent Review Decision from Texas Medical Foundation, patient blacked out, dated 10/15/03, 2 pages
Notice of Independent Review Decision from Forte, patient blacked out, dated 10/22/03, 3 pages
Notice of Independent Review Decision from Medical Review of Texas, patient blacked out, dated 8/26/03, 4 pages
Notice of Independent Review Decision from Texas Medical Foundation, patient blacked out, dated 10/22/03, 3 pages

Summary of Treatment/Case History:
By history the patient is 49-year-old gentleman initially referred regarding an on-the-job motor vehicle accident in ___. Prior to the accident, he said he had some intermittent low back pain, but had not had previous MRI studies or significant symptomatology. After the accident, he developed neck pain with episodic radiation toward the trapezius, mid-thoracic pain and low back pain that radiates toward the left leg. He was very active before, cycling. He says that he has gained 20 lb. and that the injury has "altered his lifestyle significantly." Symptoms are worsened by sitting and driving and improved somewhat by stretching, light exercise, heat and massage. Conservative care has included various medications, physical therapy, Botox, and steroid injections. In spite of this, symptoms have persisted. In October of 1999, he had a lumbar MRI scan that showed some degenerative changes at L3-4, L4-5, and L5~S1. Cervical and thoracic MRI scans performed this year showed multilevel degenerative change with a disc protrusion at C3-4. A thoracic study showed no evidence of disc herniation. There has been no alteration of bowel or bladder habits.
Impression at that time was of 1) Cervical mechanical pain with some elements in the history suggesting radiculopathy. There is however no evidence of major radiculopathy or myelopathy on physical exam, 2) Thoracic region pain probably on the basis of degenerative change and muscle strain and 3) Lumbar pain with some elements in the history suggesting radiculopathy.

On exam was well developed, well nourished with a mesomorphic body habitus. He was well groomed. There was normal affect. There were no external deformities. He was alert and oriented times three with fluent speech. Gait was independent. Station was normal. Coordination was normal in the extremities. Examination of the skin revealed no evidence of cyanosis, clubbing or edema. Range of motion of the cervical and lumbar spines were mildly limited in all directions. There was no Spurling or Lhermitte phenomenon. Motor testing was intact in the extremities. Sensation was intact to pinprick in

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the extremities. Deep tendon reflexes were symmetrically normoactive in the extremities. There were no pathologic reflexes seen. A lumbar MRI study performed 11/19 documented a right paracentral disc herniation at L4-5, though during his office visit 11/05/02, he noted left-sided radicular symptoms. A cervical MRI scan dated June 2 documented abnormalities from C2 to 7. As part of his pain management a RS-4i Sequential Stimulator has been recommended.

Questions for Review:

1) Please address prospective medical necessity of the proposed purchase of an RS4i sequential 4-channel combination interferential & muscle stimulator regarding the above mentioned injured worker.

Explanation of Findings:

1) Please address prospective medical necessity of the proposed purchase of an RS4i sequential 4-channel combination interferential & muscle stimulator regarding the above mentioned injured worker.

ACOEM Guidelines Chapters 8 thru 12 do not endorse the use of interferential stimulators due to the lack of peer-reviewed literature. The RS-4i Sequential Stimulator is investigational and is not medically necessary. There is no good Class 1 Data to support its use. Non-certification is issued based on ACOEM Guidelines. In particular, there is inadequate data from controlled clinical trials to validate the clinical efficacy of interferential stimulation. Accordingly, I am unable to justify the medical necessity of the proposed RS-4i stimulator. The disputed RS-4i stimulator does not meet medical necessity guidelines. Accordingly, pre authorization should not be granted for this device. A review of published research, federal agency positions, and MRD, IRa and SOAH decisions reveals that the use of the RS-4i stimulator has not been accepted as the prevailing standard of care. This is especially true where, as in this case, the patient suffers from a "chronic pain"-type condition.

With regard to published research, there is only one study published describing a successful response with the use of an RS-4i stimulator for low back pain (not cervical pain) at 2 months and 6 months. *See* Glaser, JA, et al, Electrical Muscle Stimulation as an Adjunct to Exercise in the Treatment of Non-acute Low Back Pain; a randomized Trial. Journal of Pain 2001: 2: 295-300. However, this study was supported by a grant from the RS Medical Corporation, the Provider in this case. The study is described as a prospective randomized double-blind and placebo controlled. Unfortunately, 42 patients of the original 80 dropped out over the 6 month study period. Thus, the number of 38 patients, 21 with RS-4i and 17 as placebo, is too small a number to generalize as being effective for all patients with lumbar or cervical pain, notwithstanding the obvious conflict of interest resulting from the grant from the manufacturer of this item. Regardless, the authors agreed that further investigation was needed. Thus, the RS-4i can be considered an appliance under investigation at this time, and does not meet criteria for medical necessity.

Conclusion/Decision to Not Certify:

I do not certify the proposed use of the RS-4i Sequential Stimulator

References Used in Support of Decision:

1. Akai M. Kawashima N. Kimura T. Hayashi K. Electrical stimulation as an adjunct to spinal fusion: a meta-analysis of controlled clinical trials. Bioelectromagnetics. 23(7):496-504, 20

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2. Uzerman MJ. Reuzel RP. Severens HL. Pre-assessment to assess the match between cost-effectiveness results and decision makers' information needs: an illustration using two cases in rehabilitation medicine in The Netherlands. [Journal Article] International Journal of Technology Assessment in Health Care. 19(1):17-27, 2003
3. Boden SD. The biology of posterolateral lumbar spinal fusion. Orthopedic Clinics of North America. 29(4):603-19, 1998
4. Mooney V. Gulick J. Perlman M. Levy D. Pozos R. Leggett S. Resnick D. Relationships between myoelectric activity, strength, and MRI of lumbar extensor muscles in back pain patients and normal subjects. Journal of Spinal Disorders. 10(4):348-56, 1997
5. Pengel HM. Maher CG. Refshauge KM. Systematic review of conservative interventions for subacute low back pain. Clinical Rehabilitation. 16(8):811-20, 2002
6. Hsieh RL. Lee WC. One-shot percutaneous electrical nerve stimulation vs. transcutaneous electrical nerve stimulation for low back pain: comparison of therapeutic effects. American Journal of Physical Medicine & Rehabilitation. 81(11):838-43, 2002
7. Gore D. Low back pain therapy ineffective? WMJ. 101(3):4, 2002
8. Rushton DN. Electrical stimulation in the treatment of pain. Disability & Rehabilitation. 24(8):407-15, 2002 May 20
9. Li LC. Bombardier C. Physical therapy management of low back pain: an exploratory survey of therapist approaches. Physical Therapy. 81(4):1018-28, 2001
10. Kaplan EA. Percutaneous electrical nerve stimulation for treatment of low back pain. JAMA. 282(10):941-2, 1999
11. Hyman MH. Percutaneous electrical nerve stimulation for treatment of low back pain. JAMA. 282(10):941-2, 1999
12. Werners R. Pynsent PB. Bulstrode CJ. Randomized trial comparing interferential therapy with motorized lumbar traction and massage in the management of low back pain in a primary care setting. Spine. 24(15):1579-84, 1999
13. Ghoname EA. Craig WF. White PF. Ahmed HE. Hamza MA. Henderson BN. Gajraj NM. Huber PJ. Gatchel RJ. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. JAMA. 281(9):818-23, 1999
14. Zytkowski A. Ectodermal method of Ryodorak--an attempt at clinical measurement for evaluation of physiotherapy effects in patients with low back pain. Neurologia Neurochirurgia Polska. 32 Suppl 6:207-15, 1999
15. Hamza MA. Ghoname EA. White PF. Craig WF. Ahmed HE. Gajraj NM. Vakharia AS. Noe CE. Effect of the duration of electrical stimulation on the analgesic response in patients with low back pain. Anesthesiology. 91(6):1622-7, 1999

The physician providing this review is board certified in Neurological Surgery (1997). The reviewer has additional certification from the American Board of Pediatric Neurosurgery (1998) The physician is a member of the American Medical Association, the Congress of Neurological Surgeons, the American Association of Neurological Surgeons, the Society of University Neurosurgeons and the American College of Surgeons. The reviewer has served on the editorial boards for Neurosurgery and Journal of

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Neurosurgery: Focus. The reviewer has served as a clinical instructor and Assistant Professor of Neurosurgery at the university level. The reviewer is currently an associate professor at the university level. The reviewer has extensive publishing and presentation within their field of specialty. The reviewer has been in active practice since 1986.

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 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.

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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