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DATE OF REVIEW:

May/06/2009

IRO CASE #:**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Purchase of RS-2m stimulator and supplies

DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

MD, Board Certified in Physical Medicine and Rehabilitation
Board Certified in Pain Management
Board Certified in Electrodiagnostic Medicine

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Overturned (Disagree)

Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

ODG Guidelines and Treatment Guidelines
Adverse Determination Letters, 3/27/09, 4/3/09
RS Medical, Request for Authorization, 3/23/09
RS Medical, Prescription, 9/25/08
Pain Consultant Associates, MD, 4/15/09, 3/11/09, 2/4/09, 11/26/08, 1/7/09, 10/22/08, 9/24/08, 8/20/08, 7/16/08

PATIENT CLINICAL HISTORY SUMMARY

This is a male patient with a history of chronic pain secondary to degenerative disc disease of the lumbar spine. He has a previous compression fracture of L2 vertebra, as a result of a work injury in xxxx. In the February 2009 note it is noted that his pain comes with exertion, with prolonged sitting or walking. He is also being treated with medication management with hydrocodone four times per day, and has been compliant as per the 4/15/09 doctor's note. The 4/15/09 note from the doctor says, "In light of his stable condition without exacerbation, I will continue medication management and I have encouraged him to continue modalities and stretching exercises on his own. We will get urine sample to verify compliance. I will see him back in five weeks for reassessment."

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDING CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION

The RS is a muscle stimulator and interferential current. There is nothing in the medical

records provided for this review that would justify the use of this device. The request does not meet the guidelines. The reviewer finds that medical necessity does not exist for Purchase of RS-2m stimulator and supplies.

Interferential current stimulation (ICS)

Not recommended as an isolated intervention. There is no quality evidence of effectiveness except in conjunction with recommended treatments, including return to work, exercise and medications, and limited evidence of improvement on those recommended treatments alone. The randomized trials that have evaluated the effectiveness of this treatment have included studies for back pain, jaw pain, soft tissue shoulder pain, cervical neck pain and knee pain. (1999) (1999) (2001) (2002) (2003) (2004) (2005) (, 2008) The findings from these trials were either negative or insufficient for recommendation due to poor study design and/or methodologic issues. In addition, although proposed for treatment in general for soft tissue injury or for enhancing wound or fracture healing, there is insufficient literature to support Interferential current stimulation for treatment of these conditions. There are no standardized protocols for the use of interferential therapy; and the therapy may vary according to the frequency of stimulation, the pulse duration, treatment time, and electrode-placement technique. Two recent randomized double-blind controlled trials suggested that ICS and horizontal therapy (HT) were effective in alleviating pain and disability in patients with chronic low back pain compared to placebo at 14 weeks, but not at 2 weeks. The placebo effect was remarkable at the beginning of the treatment but it tended to vanish within a couple of weeks. The studies suggested that their main limitation was the heterogeneity of the low back pain subjects, with the interventions performing much better for back pain due to previous multiple vertebral osteoporotic fractures, and further studies are necessary to determine effectiveness in low back pain from other causes. (2006) (2007) A recent industry-sponsored study in the Knee Chapter concluded that interferential current therapy plus patterned muscle stimulation (using the RS-4i Stimulator) has the potential to be a more effective treatment modality than conventional low-current TENS for osteoarthritis of the knee. (2008) This recent RCT found that either electroacupuncture or interferential electrotherapy, in combination with shoulder exercises, is equally effective in treating frozen shoulder patients. It should be noted that this study only showed the combined treatment effects with exercise as compared to no treatment, so the entire positive effect could have been due to the use of exercise alone. (2008) See also Sympathetic therapy. See also TENS, chronic pain

How it works: Paired electrodes of two independent circuits carry differing medium-frequency alternating currents so that current flowing between each pair intersects at the underlying target. The frequency allows the Interferential wave to meet low impedance when crossing the skin. Treatments involve the use of two pairs of electrodes and most units allow variation in waveform, stimulus frequency and amplitude or intensity, and the currents rise and fall at different frequencies. It is theorized that the low frequency of the interferential current causes inhibition or habituation of the nervous system, which results in muscle relaxation, suppression of pain and acceleration of healing.

How it is different than TENS: It has been postulated that Interferential stimulation allows for deeper penetration of tissue, whereas TENS is predominantly a cutaneous or superficial stimulus. Interferential current is proposed to produce less impedance in the tissue and the intensity provided is suggested to be perceived as more comfortable. Because there is minimal skin resistance with the interferential current therapy, a maximum amount of energy goes deeper into the tissue. It also crisscrosses, as opposed to the linear application of the TENS. This crisscrossing is postulated to be more effective because it serves to confuse the nerve endings, preventing the treated area from adjusting to the current. There are no published randomized trials comparing TENS to Interferential current stimulation.

Current US treatment coverage recommendations: Health plans have taken a variety of positions with respect to ICS. California Technology Assessment Forum concluded that the treatment does not meet their criteria for coverage. (CTAF, 2005) Aetna considers it experimental because its effectiveness has not been established. (Aetna, 2007) United Healthcare concluded that clinical evidence supports its use for treatment of pain or non-surgical soft tissue injuries. (United, 2007) Humana provides coverage for acute postoperative or post-traumatic pain, or chronic pain of at least three months duration that is not responsive to other methods of pain management. (Humana, 2008) There is considerable variance in the Blue Cross/Blue Shield coverage recommendations, and some BC/BS licensees reference ICS as investigational/not medically necessary (BlueCross BlueShield, 2006), but others do cover it. (BC/BS_TN, 2008) CMS does not directly address its use. In workers' comp, Washington L&I covers these devices, but only from a single TENS supplier. (Washington, 2008) [Note: Coverage determinations by health insurance plans are not considered high quality evidence in formulating ODG recommendations, but may be provided for reference when high quality studies are not available.

While not recommended as an isolated intervention, Patient selection criteria if Interferential stimulation is to be used anyway

Possibly appropriate for the following conditions if it has documented and proven to be effective as directed or applied by the physician or a provider licensed to provide physical therapy

- Pain is ineffectively controlled due to diminished effectiveness of medications; or
- Pain is ineffectively controlled with medications due to side effects; or
- History of substance abuse; or
- Significant pain from postoperative or acute conditions limits the ability to perform exercise programs/physical therapy treatment; or
- Unresponsive to conservative measures (e.g., repositioning, heat/ice, medications, etc.).

If those criteria are met, then a one-month trial may be appropriate to permit the physician and physical therapy provider to study the effects and benefits. There should be evidence of increased functional improvement, less reported pain and evidence of medication reduction

A "jacket" should not be certified until after the one-month trial and only with documentation that the individual cannot apply the stimulation pads alone or with the help of another available person.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION

ACOEM-AMERICA COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

AHCPR-AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES

DWC-DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN

INTERQUAL CRITERIA

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

MILLIMAN CARE GUIDELINES

ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

TEXAS TACADA GUIDELINES

TMF SCREENING CRITERIA MANUAL

PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)