

Clear Resolutions Inc.

An Independent Review Organization

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Notice of Independent Review Decision

DATE OF REVIEW: DECEMBER 26, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Transcutaneous electrical nerve stimulation unit purchase from EMPI.

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

M.D., Board Certified Orthopedic Surgeon

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

Records of medical visits from 04/25/01 to 07/10/03
Office notes, Dr. 02/27/07, 07/30/07, 08/13/07, 09/04/07, 10/03/07, 12/12/07
Office notes, Dr., 03/02/07, 06/18/07
Right leg CT scan, 03/06/07
Bone scan, 04/09/07
Office note, Dr., 07/03/07
Physical therapy order, Dr. , 07/30/07
Prescription, Dr. , 07/30/07
Pre-authorization decision, 09/11/07
Utilization review, 10/11/07, 11/08/07

Letter of appeal, Dr., 10/30/07

Official Disability Guidelines Treatment in Worker's Comp 2007 Updates, Pain: TENS, chronic pain

PATIENT CLINICAL HISTORY [SUMMARY]:

This xx year old female sustained a crush injury to her legs on xx/xx/xx with hematomas of the lower legs. She required evacuation of a right knee hematoma following the injury. She had subsequent neuropathic pain of her lower extremities secondary to nerve damage from the injury. She treated with pain management Dr. and a spinal cord stimulator as inserted in 2004. The claimant remained working. She continued to follow with Dr.

On 02/27/07 she was seen by Dr., medical physician, for a mass in the right lower leg with redness, swelling and pain. Per the 03/02/07 visit with Dr., medications included OxyContin, Ultram, Lidoderm patch and Lexapro. A CT scan of the right leg on 03/06/07 showed no significant bony or soft tissue abnormality. A bone scan of 04/09/07 showed a mild increased uptake localizing to the left medial malleolus of uncertain significance. The right leg and foot were within normal limits. At the 06/18/07 visit with Dr., pinprick was diminished in the right L4 distribution. The claimant had an antalgic limp on the right. The diagnosis was leg pain, neuropathy and chronic regional pain syndrome of the lower limb. Dr. noted that the mass seemed subarticular and stretching of the Achilles was not painful. He referred the claimant for orthopedic evaluation.

Dr., orthopedic surgeon, examined the claimant on 07/03/07 for persistent pain in the right calf located about 4 inches above the attachment point. He noted that an MRI of the Achilles tendon showed no tear. He recommended physical therapy for stretching, heat and interferential treatment. He felt that the claimant had a fascial tear over the area of the muscle with fibrosis secondary to the original compression injury. He discussed surgical exploration if therapy failed but recommended 3 months of therapy to work on flexibility and strengthening. Four weeks of physical therapy was approved beginning 07/19/07.

Dr. noted on a follow up visit of 07/30/07 that the right leg pain was rated 9/10 and located just above the medial malleolus up to the proximal third of the leg along the Achilles tendon. He recommended continued therapy and ordered a TENS unit. A one month rental trial of a TENS unit was approved from 09/11/07 to 10/11/07.

The claimant was seen on 10/03/07 by Dr.. The nurses notes stated that the pain was increased in the right lower extremity. The claimant was working. Dr. documented a 9/10 level of pain. She was using the TENS on her leg for about 30 minutes in the morning and evening. She still had an area of edema just above the ankle posteriorly. The diagnosis was right leg sprain with gastrocnemius strain – rule out micro tears. Purchase of the TENS unit was denied on utilization review. Dr. authored a letter of appeal dated 10/30/07 in which he indicated that the claimant had used the TENS for a month with very good results alternating it with a spinal cord stimulator. Purchase of the TENS unit was again denied on utilization review. An office note dated 12/12/07 from Dr. indicated that the burning sensation in the right leg was getting worse. The claimant had seen Dr. but his report was not available. The notes were hand written and most of them were not legible. The treatment plan was for CT angio of the right lower extremity for a diagnosis of post traumatic blood clot.

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

There is no documentation within the orthopedic literature or peer reviewed journals that substantiate the medical necessity for TENS units. There was a one month trial of a TENS unit from 09/11/07 to 10/11/07. There was no subjective or objective change in the claimant's clinical condition following this trial of TENS use. Therefore, I do not think it is reasonable and appropriate to undertake purchase of the TENS unit. This is consistent with ODG guidelines.

Official Disability Guidelines Treatment in Worker's Comp 2007 Updates, Pain: TENS, chronic pain.

Not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, for the conditions described below. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. (Carroll-Cochrane, 2001) Several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. One problem with current studies is that many only evaluated single-dose treatment, which may not reflect the use of this modality in a clinical setting. Other problems include statistical methodology, small sample size, influence of placebo effect, and difficulty comparing the different outcomes that were measured.

Recommendations by types of pain: A home-based treatment trial of one month may be appropriate for neuropathic pain and CRPS II (conditions that have limited published evidence for the use of TENS as noted below), and for CRPS I (with basically no literature to support use).

Neuropathic pain: Some evidence (Chong, 2003), including diabetic neuropathy (Spruce, 2002) and post-herpetic neuralgia. (Niv, 2005)

Criteria for the use of TENS:

Chronic intractable pain (for the conditions noted above):

- Documentation of pain of at least three months duration
- There is evidence that other appropriate pain modalities have been tried (including medication) and failed
- A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial
- Other ongoing pain treatment should also be documented during the trial period including medication usage
- A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted
- A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary

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

- ACOEM- AMERICAN 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)
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