



REVIEWER'S REPORT

DATE OF REVIEW: April 18, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OF SERVICES IN DISPUTE:

Two months rental (extension of prior rental) of RS-4i sequential stimulator (interferential stimulator)

QUALIFICATIONS:

MD, Board-certified in neurology, board-eligible in electroencephalography

REVIEW OUTCOME:

Upon independent review, I find that the previous adverse determination or determinations should be (check only one):

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED FOR REVIEW:

1. URA findings, February 26, 2007 to March 1, 2007
2. Medical prescription and pre-authorization request, January 16, 2007
3. Letter of medical necessity January 16, 2007
4. Undated literature on the requested modality, 2 pages
5. TDI referral

INJURED EMPLOYEE CLINICAL HISTORY (Summary):

Male respiratory therapist injured lifting patients in a health care setting. The resulting back injury has been treated for two months with either a TENS unit (as described by his physician on 2/7/07) or an interferential stimulator RS-4i (as the same physician has requested in writing to the insurer). The physician has requested a two-month extension of the rental of the device. There was no objective evidence provided in the medical record that that the initial two months of the device had raised his pain threshold or lowered his need for pain medication. There was confusion in the record as

to which device was being requested, between the medical record and the request for insurance coverage.

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

The date of injury and immediately subsequent treatments and response to those therapies are entirely unknown from the material provided. It is unknown whether standard therapies were initially applied. The term used for the low pain injury was 'lumbago,' an older term that does not specify the type or nature of the back injury. The physician seems to have confused TENS therapy, well accepted for chronic pain relief, with interferential stimulation, a controversial and not well tested or proven therapy. Which one has been applied and which is being sought to be continued is unclear from the medical documentation.

The medical literature on interferential stimulation is sparse in terms of peer-reviewed comparison studies of effectiveness. The only study (Clin Exp Rheumatol. 2006 Sep-Oct;24(5):534-9. Interferential and horizontal therapies in chronic low back pain: a randomized, double blind, clinical study. Zambito A, Bianchini D, Gatti D, Viapiana O, Rossini M, Adami S.) that performs a comparison studied a population for up to 14 weeks and found some benefit in that time. There is no other strong supporting literature yet for chronic low back pain.

The current request is to extend (presumably) the RS-4i rental beyond the first 8 weeks to a second 8 weeks. There is no objective evidence that the first eight weeks were effective, any more than rest and medication. In fact, there is no evidence that any standard back care program was applied to help this patient. He in fact was back at work lifting patients according to the record and suffered a re-injury.

The patient deserves a trial on standard therapies (heat and cooling), anti-inflammatory medication, a concerted effort at weight loss, physical therapy and some pain medication with attempted reduction before the more exotic therapies are applied.

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

- ACOEM 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 judgment, clinical experience and expertise in accordance with accepted medical standards
- Mercy Center Consensus Conference Guidelines
- Milliran 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 (with description)
- x Other evidence-based, scientifically valid, outcome-focused guidelines (with description)

Clin Exp Rheumatol. 2006 Sep-Oct;24(5):534-9.

Interferential and horizontal therapies in chronic low back pain: a randomized, double blind, clinical study.

Zambito A, Bianchini D, Gatti D, Viapiana O, Rossini M, Adami S.

OBJECTIVE: Chronic Low Back Pain (CLBP) is one of the most frequent medical problems. Electrical nerve stimulation is frequently used but its efficacy remains controversial. **METHODS:** Twenty-six men and 94 women with CLBP associated with either degenerative disk disease or previous multiple vertebral osteoporotic fractures were randomly assigned to either interferential currents (IFT), horizontal therapy (HT) or sham HT administered for 10, 40 and 40 minutes, respectively, daily for 5 days per week for two weeks together with a standard flexion-extension stretching exercise program. Blind efficacy assessment were obtained at baseline and at week 2, 6 and 14 and included a functional questionnaire (Backill), the standard visual analog scale (VAS) and the mean analgesic consumption. **RESULTS:** At week 2 a significant and similar improvement in both the VAS and Backill score was observed in all three groups. The Backill score continued to improve only in the two active groups with changes significantly greater than those observed in control patients at week 14. The pain VAS score returned to baseline values at week 6 and 14 in the control group while in the IFT and HT groups it continued to improve ($p < 0.01$ vs controls). The use of analgesic medications significantly improved at week 14 versus pretreatment assessment and over control patients only in the HT group. **CONCLUSION:** This randomized double-blind controlled study provides the first evidence that IFT and HT therapy are significantly effective in alleviating both pain and disability in patients with CLBP. The placebo effect is remarkable at the beginning of the treatment but it tends to vanish within a couple of weeks.

PMID: 17181922 [PubMed - indexed for MEDLINE]

Pain. 2005 May;115(1-2):152-60.

Segmental noxious versus innocuous electrical stimulation for chronic pain relief and the effect of fading sensation during treatment.

Defrin R, Ariel E, Peretz C.

It is not clear whether segmental innocuous stimulation has a stronger analgesic effect than segmental noxious stimulation for chronic pain and whether the fading of current sensation during treatment interferes with the analgesic effect, as suggested by the gate control theory. Electrical stimulation (by way of Interferential Current) applied at the pain area (segmental) was administered to 4 groups of patients with osteoarthritis (OA) knee pain. Two groups were administered with noxious stimulation (30% above pain threshold) and two with innocuous stimulation (30% below pain threshold). In each group half of the patients received a fixed current intensity while the other half raised the

intensity continuously during treatment whenever fading of sensation was perceived. Group 5 and 6 received sham stimulation and no treatment, respectively. The outcome measures were: chronic pain intensity, morning stiffness, range of motion (ROM), pain threshold and % pain reduction. Both noxious and innocuous stimulation significantly decreased chronic pain ($P < 0.001$) and morning stiffness ($P < 0.01$) and significantly increased pain threshold ($P < 0.001$) and ROM ($P < 0.001$) compared with the control groups. Nevertheless, noxious stimulation decreased pain intensity ($P < 0.05$) and increased pain threshold ($P < 0.001$) significantly more than innocuous stimulation. No differences in treatment outcomes were found between adjusted and unadjusted stimulation. (a) Interferential current is very effective for chronic OA knee pain, (b) segmental noxious stimulation produces a stronger analgesic effect than segmental innocuous stimulation, (c) the fading of sensation during treatment, does not decrease the analgesic effect. Possible mechanisms explaining the findings are discussed.
PMID: 15836978 [PubMed - indexed for MEDLINE]

Spine. 2004 Oct 15;29(20):2207-16.

A randomized clinical trial of manipulative therapy and interferential therapy for acute low back pain.

Hurley DA, McDonough SM, Dempster M, Moore AP, Baxter GD.

STUDY DESIGN: A multicenter assessor-blinded randomized clinical trial was conducted. **OBJECTIVES:** To investigate the difference in effectiveness of manipulative therapy and interferential therapy for patients with acute low back pain when used as sole treatments and in combination. **SUMMARY OF BACKGROUND DATA:** Both manipulative therapy and interferential therapy are commonly used treatments for low back pain. Evidence for the effectiveness of manipulative therapy is available only for the short-term. There is limited evidence for interferential therapy, and no study has investigated the effectiveness of manipulative therapy combined with interferential therapy. **METHODS:** Consenting subjects ($n = 240$) recruited following referral by physicians to physiotherapy departments in the (government-funded) National Health Service in Northern Ireland were randomly assigned to receive a copy of the Back Book and either manipulative therapy (MT; $n = 80$), interferential therapy (IFT; $n = 80$), or a combination of manipulative therapy and interferential therapy (CT; $n = 80$). The primary outcome was a change in functional disability on the Roland Morris Disability Questionnaire. Follow-up questionnaires were posted at discharge and at 6 and 12 months. **RESULTS:** The groups were balanced at baseline for low back pain and demographic characteristics. At discharge all interventions significantly reduced functional disability (Roland Morris scale, MT: -4.53; 95% CI, -5.7 to -3.3 vs. IFT: -3.56; 95% CI, -4.8 to -2.4 vs. CT: -4.65; 95% CI, -5.8 to -3.5; $P = 0.38$) and pain (McGill questionnaire, MT: -5.12; 95% CI, -7.7 to -2.5 vs. IFT: -5.87; 95% CI, -8.5 to -3.3 vs. CT: -6.64; 95% CI, -9.2 to -4.1; $P = 0.72$) and increased quality of life (SF-36 Role-Physical, MT: 28.6; 95% CI, 18.3 to 38.9 vs. IFT: 31.4; 95% CI, 21.2 to 41.5 vs. CT: 30; 95% CI, 19.9 to 40; $P = 0.93$) to the same degree and maintained these improvements at 6 and 12 months. No significant differences were found between groups for reported LBP recurrence, work absenteeism, medication consumption, exercise participation, or healthcare use at 12 months ($P > 0.05$). **CONCLUSIONS:** For acute low back pain, there was no difference between the effects of a combined manipulative therapy and

interferential therapy package and either manipulative therapy or interferential therapy alone.

PMID: 15480130 [PubMed - indexed for MEDLINE]