MedHealth **R**eview, **I**nc.
661 E. Main Street
Suite 200-305
Midlothian, TX 76065
Ph 972-921-9094
Fax 972-775-6056

Notice of Independent Review Decision

DATE OF REVIEW: 5/3/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
The item in dispute is the prospective medical necessity of a trial of a spinal cord stimulator.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. This reviewer has been practicing for greater than 15 years.

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)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of a trial of a spinal cord stimulator.

INFORMATION PROVIDED TO THE IRO FOR REVIEW
Records were received and reviewed from the following parties: xxxxx, xxxxx

These records consist of the following (duplicate records are only listed from one source): Records reviewed from xxxxx: Denial letters – 3/8/10 & 3/25/10;

xxxxx letter – 3/18/10, Authorization – 2/26/10, Patient Demographics – undated, Referral request – 2/25/10, Operative reports – 10/7/08-2/27/09; xxx xxxxx letter – 3/3/10; Patient Overview (71pgs)– 3/1/10.
Records reviewed from xxxxx: Office Notes – 10/31/08-3/16/10; xxxxxMRI xxxxx – 7/14/08; and MD Neuro Diagnostic report – 9/18/09.
Records reviewed from Ph.D. Psych Eval – 2/23/10.

A copy of the ODG was not provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:
The 3/8/10 dated denial letter denoted that the sustained a back injury while utilizing a jackhammer. There were complaints of back pain with parasthesias and weakness in the legs. A 7/14/08 dated MRI revealed narrowing and retrolisthesis at L4-5 with disc protrusion, with disc protrusion + annular tear at L5-S1. Left knee and ankle jerks were 1+ and zero respectively, with +SLR. .Bilateral EHL's were 4/5Treatment included ESI's, facet blocks and ablation, along with "lumbar surgery." A stimulator trial was considered. The denial rationale was that neither the claimant's surgical procedure nor post-op treatment was adequately delineated to support a diagnosis of failed syndrome or indication for a stimulator. The 3/25/10 dated reconsideration-denial letter utilized the same rationale.
The 3/18/10 dated "response to denial" letter indicated that the 5/09 dated lumbar surgery "corrected the anatomical problem but left him with severe and consistent pain…pain to his low back radiating down the bilateral legs...post-laminectomy syndrome." The 3/3/10 dated letter discussed the claimant's "chronic intractable pain that is refractory to standard treatment…" Prior treatment notes were reviewed, including documentation of injections, ablations etc., along with diagnoses including "chronic pain..neuritis." Recent progress notes from 3/10 and 4/10 were reviewed. Ongoing medications included Darvocet and Flexeril. Prior ESI results (from the fall 2008) documented significant relief at 6 weeks post injection but poor relief from a 5/09 dated surgical procedure. Medications included Amitryptiline, Lidoderm patches and Lyrica. The 7/14/08 dated MRI report was reviewed.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.
There has been inadequate documentation of what type of surgical procedure had been performed and had failed. Failed Back Syndrome has not been established as a diagnosis. In addition, there has not been recent evidence of failure of ESI's, which had evidence of reasonable prior efficacy. Therefore, there are possible alternative medical and surgical intervention treatments whose efficacy cannot be ruled out and may or may not have even been tried and/or failed. A spinal stimulator trial is premature and not medically necessary at this

time as less invasive procedures have not been adequately documented or delineated to have failed or to be contraindicated.

According to the ODG: Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the Pain Chapter for *Indications for stimulator implantation*. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in the past five years has it met with widespread acceptance and recognition by the medical community. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain diagnoses, probably indiscriminately. The results at follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There are several reasons for this development, the principal one being that the indications have been more clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to CMM for FBSS. See the Pain Chapter for complete list of references. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the recently released joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. The National Institute for Health and Clinical Excellence (NICE) of the UK just completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management.
Recent research: New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. There is

fair evidence that spinal cord stimulation is moderately effective for failed back surgery syndrome with persistent radiculopathy, though device-related complications are common.

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)**