



Specialty Independent Review Organization

Notice of Independent Review Decision

Date notice sent to all parties: 2/4/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

The item in dispute is the prospective medical necessity of a replacement of stimulator battery.

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.

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 replacement of stimulator battery.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source): Records reviewed:

letter – 1/21/13
ODG – Spinal Cord Stimulation Section

Denial Letters – 12/28/12, 1/10/13

Pre-authorization Request – 12/21/12
Patient Information sheet – 12/20/12
Neurostimulator Report – 12/20/12

Progress Notes – 2/27/09, 3/12/09, 7/7/09, 7/1/10, 10/25/10, 5/17/12,
6/22/12, 12/20/12

Consultation Report – 4/19/12

Chart Note – 2/6/09

Operative Report – 5/9/12

CT L-Spine w/ Contrast Report – 6/18/12

Records reviewed:

Device Specific Information x2 – undated

Program myStim – 9/27/11

A copy of the ODG was provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant was injured xx years ago. The injury was associated with a motor vehicle accident. The claimant's spinal cord stimulator battery was replaced seven months ago on 5/9/12. The operative summary was reviewed and it was noted that the claimant's postoperative pain was attributable to "post-laminectomy syndrome." The Attending Physician records were reviewed in detail. The most recent clinical note was dated 12/20/12. It reflected that the patient desires to have the battery replaced. Disc bulging, fissures and spondylosis had been noted at multiple lumbar levels on the CT-discogram report dated 6/18/12. Denial letters noted the lack of findings evidencing a medical indication for a replacement of battery, and that typically such batteries are functional for multiple years.

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

The records do not reflect a combination of subjective and-or objective findings that evidence that the stimulator battery had become nonfunctional. In addition, the request is rather inexplicable in light of the previous similar replacement seven months ago. As noted in the applicable clinical guideline criteria, "The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure." Therefore, both in general and specifically with regard to details of the findings within the provided records; the prospective medical necessity of replacement of stimulator battery has not been reasonably documented to meet guideline criteria and is not medically necessary at this time.

ODG Low Back- Spinal Cord Stimulation: 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. (Chou, 2008) 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. (NICE, 2008)

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. (Kumar, 2008) 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. (Chou3, 2009) A nonrandomized, prospective cohort study in workers comp patients with chronic back and leg pain after spine surgery, i.e. failed back surgery syndrome (FBSS), found no significant difference in pain, disability, or opioid use between patients that received (at least a trial of)

SCS, care at a pain clinic, or neither (usual care) at 12 and 24 months. Only 25% of SCS patients in this study received psychological screening prior to the trial, whereas ODG recommends psychological screening prior to all SCS implantations.

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)**