



Specialty Independent Review Organization

Notice of Independent Review Decision

Date notice sent to all parties: 5/20/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

The item in dispute is the prospective medical necessity of a permanent 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.

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 permanent spinal cord stimulator.

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:

Denial Letters – 3/18/13, 4/9/13

Patient Encounter Notes – 8/8/12, 8/22/12, 9/19/12, 10/17/12, 11/14/12,
12/12/12, 1/11/13, 2/20/13, 2/25/13
Procedure Note – 2/19/13

Psychological Evaluation Report – 9/27/12

Lumbar MRI – 9/17/10

Follow-up Notes – 11/2/11, 12/7/11, 4/18/12

Reconsideration Letter – 9/6/12

History and Physical – 2/22/11

Operative Report – 11/4/08, 2/22/11, 2/28/11

Records reviewed:

Anesthesia Record – 2/28/11

Pre-Anesthesia Record – 2/28/11

External Bone Growth Stimulator Script – 4/24/12

Follow-up Notes – 6/27/11, 10/12/11

PPE Reports – 5/25/12, 8/29/12

FCE Reports – 5/25/12, 8/29/12

Physician Referral – 12/7/11, 5/22/12

Physical Therapy Consultation – 5/23/12

Individual Therapy Progress Notes – 5/30/12, 6/19/12, 6/25/12, 6/28/12,
7/23/12, 7/25/12, 8/1/12, 8/7/12, 8/9/12

Group Therapy Progress Notes – 6/19/12, 6/20/12, 6/25/12, 6/27/12,
6/28/12, 7/23/12, 7/25/12, 7/26/12, 8/1/12, 8/2/12, 8/7/12, 8/9/12

Patient Information – undated

Approval Letters – 6/7/12, 7/12/12

Chronic Pain Management Program Super Bill/Daily Charge Slips – 6/2/12,
6/19/12, 6/25/12, 6/27/12, 6/28/12, 7/23/12, 7/25/12, 7/26/12, 8/1/12,
8/2/12, 8/7/12, 8/9/12

Chronic Pain Management Program Daily Documentation Sheet for Physical
Rehab – 6/19/12, 6/20/12, 6/25/12, 6/27/12, 6/28/12, 7/23/12, 7/26/12,
8/1/12, 8/2/12, 8/7/12, 8/7/12

Chronic Pain Program Notes – 6/19/12-8/13/12

Chronic Pain Management Program Interdisciplinary Team Progress Reports –
7/5/12, 8/16/12

Office/Outpatient Visit – 7/12/12

PPE Report – 6/3/11

Triage Notes – 3/17/10, 6/2/10

Texas Department of Insurance:

Letter of Clarification – 7/19/11

DDE Report – 7/19/11

MMI Report – 7/19/11
DWC69 – 7/5/11

Laboratory Report – 8/20/12

Conditions of Admission – 4/27/11

Emergency Department General Instructions – 4/27/11

Emergency Room Notes – 4/27/11

MR Lumbar Spine w/ & w/o Contrast – 4/27/11

Chemistry Report – 4/27/11

Medication Discharge Summary – 4/28/11

Discharge Report – 4/27/11

Peer Review – 9/21/11

Evaluation Report – 7/5/11

Pre-authorization Request – 12/13/12

Records reviewed:

Established Patient Encounter Note – 4/14/13

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

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant has had ongoing low back pain with radiation to bilateral lower extremities in association with an injury sustained on xx/xx/xx. Treatments have included therapy, TNS unit, medications and surgical intervention (L4-5 fusion) along with ESIs and a 9/17/10 updated lumbar MRI report. Records from the treating provider were reviewed including the office note dated 4/12/13. The claimant was noted to have undergone a trial of spinal cord stimulation with a reported 70% relief. Exam findings have revealed a persistently positive straight leg raise with low back and gluteal region tenderness and spasms along with tenderness of the SI joint and overall decreased lumbosacral range of motion. Ongoing medications include Norco, Opana, promethazine and tizanidine. However, denial letters indicated that significant pain medication reduction and/or functionality improvement has not been documented post spinal cord stimulation.

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

The submitted documentation does not evidence any definitive increase in overall functionality and-or reduction in utilization of pain relieving medications. Without evidence of the preceding, the applicable ODG criteria have not been

met at this time. Therefore, the request cannot be considered medically necessary at this time.

ODG Low Back Chapter-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 that provided 70% relief.. 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, ie 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. Because few patients in any group in this study achieved success at any follow-up, the authors suggested that no treatment has a substantial impact on average in this patient group. (Turner, 2010)

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

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)