CASEREVIEW

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IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Spinal Cord Stimulator Trail

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
This physician specializes in Physical Medicine and Rehabilitation with over 20 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant is a XX who was injured on XX. XX was taking XX and tripped XX, falling backward onto a XX, landing on XX buttocks. Prior treatment includes cervical fusion in XX, medication management, injections, physical therapy, and activity modification. XX also has history of lumbar fusion in XX.

On XX, Myelogram & CT Impression: Status post previous posterior spinal fusion of L4-S1. Mild canal stenosis at L3-L4. 3 mm nonobstructing right renal calculs.

On XX, the claimant presented to XX, MD for worsen pain to XX neck and lower back. XX reported pain level was 8-9/10. XX denied having any numbness, tingling or weakness into XX upper and lower limbs. Medication helped to decrease XX pain whereas, increased activity increased XX pain. On examination XX ROM of the cervical spine was limited and did reproduce a radiculopathic symptom. There was no evidence of tenderness or spasm to palpation of the cervical spine. ROM of the lumbar spine was limited. There was evidence of tenderness and spasm to the lumbar spine. Straight leg raising did not reproduce radiculopathy. Diagnosis: Chronic pain syndrome, Pseudarthrosis after fusion or arthrodesis, cervical radiculopathy, and low back pain. Prescriptions: XX 10-325 mg.

On XX the claimant presented to XX, MD. XX reported XX neck pain was located central, left sided, right sided, radiating to the left and right shoulders. XX stated the pain was severe >8, not progressing, sharp, and achy. Further, the pain was constant, worse in the morning, worse at the end of the day and worse at night. XX ROM was stiff. XX stated the symptoms were increased with activity, bending forward, bending

backward, turning head to left and right, reaching out and reaching above. The symptoms were improved with activity and resting. Other symptoms included muscle spasms, numbness and tingling. The pain radiated to the left and right shoulder, elbow, forearm and hand. The low back pain was located central, left sided, right sided, radiating to the left and right buttock, hip, thigh, knee and foot. The pain was severe >8, not progressing, dull and achy. The pain was constant, worse in the morning, wore at the end of the day and worse at night. The symptoms were increased with activity, sitting,standing, getting up from a chair, bending forward, bending backwards and walking. The symptoms were improved with changing positions and lying down and medications. Other symptoms included muscle spasms, numbness, tingling and cramps. Plan: Start XX 300 mg and XX.

On XX, the claimant presented to XX, PA-C reported that XX helped but not as good as they did before andXX didn't feel much of a difference with the XX Plan: Increase XX from 300 mg to 600 mg and continue XX. Consider scs trail.

On XX, the claimant presented to XX, MD reporting that XX did not help so XX stopped taking it. XX reported neck pain was worse than lower back pain. XX denied new symptoms, change in location, character of pain, or red flag symptoms. There was no change in activity level and functioning housework. XX reported XX was interested in scs trial. Plan: Referral to Dr. XX for scs trial for neck. XX was to continue a home exercise program and XX.

On XX the claimant presented to XX for initial evaluation. XX complained of constant, moderate to severe neck pain rated 8/.10. XX had an ACDF C4-5 and C5-6 in 2013. XX reported little change with the surgery. Overall, XX pain has been increasing over the past 1-2 years. Earlier in XX, XX had a cervical CT scan and cervical MRI. CT scan showed a possible pseudoarthrosis at C4-5 and the MRI showed a bulge at C3-4. XX reported intermittent numbness and tingling into XX arms. On exam XX was very tender over the cervical paraspinal muscles. Tender over the trapezius muscles. Very limited cervical ROM. Motor strength was 5/5 through the bilateral upper extremities. Sensation was intact to light touch throughout the bilateral upper extremities. Reflexes 1+ and symmetric bilaterally. X-ray order showed a solid fusion at C5-6. A lytic line at the inferior aspect of C4-5 was noted, possible pseudoarthrosis. Arthritis was seen at C2-3 and C3-4. Plan: Repeat CT scan or possible surgery. Referred to Dr. XX for second opinion.

On XX the claimant presented to XX, PsyD for psychological evaluation. Recommendation: XX is psychologically stable, XX judgment is sound, and XX is capable of informed consent concerning the pending surgical procedure. The patient is psychologically able to tolerate this procedure and to actively participate in XX recovery. There is no evidence e of psychopathology that would make XX a poor surgical candidate.

On XX the claimant presented to CC, PA-C for continued cervical and lumbar pain rated 8/10. No change in symptoms or physical exam. Plan: Scs trail cervical and possible lumbar. XX requested to try discontinuing XX temporarily to see if it's helping. Continue PT per Dr.XX. Continue XX and home exercise program.

On XX, XX MD performed a UR. Rationale for Denial: According to the provided documentation, the patient had neck and low back pain and rated the pain as 8/10. The patient reported associated stiffness and weakness. The patient had a psychological clearance recommending clearance for a spinal cord stimulator trial. There was no evidence of abuse issues the patient has evidence of failed back surgery syndrome. There was evidence the patient had limited response to non-interventional care. However, the duration of the spinal cord stimulator trial was not provided for review. Further clarification is needed to determine the medical necessity of this request. There were limited examination findings to the lumbar spine provided for review documenting significant pathology that would benefit form a spinal cord stimulator trial for this patient. As such, this request is not appropriate for this patient.

On XX XX, MD performed a UR. Rationale for Denial: According to Official Disabilities Guidelines, a spinal cord stimulator is recommended for selected patients with specific conditions as indicated above. At this time, there has been a limited response to other invasive care, with the concerns regarding the cervical

spine fusion due to consistent reported radicular pain. There is also no indication that the patient is a risk of aberrant drug behavior, to the degree that it is noted XX wanted to stop taking the XX to see if it was actually helping with any of XX symptoms. There is also a psychological evaluation that was conducted that supports the use of the device in this patient. However, there is no indication in the request that states the duration of the trial or the desired result. Based on this information, the request for spinal cord stimulator trials is non-certified.

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

Determination: Denial of Spinal Cord Stimulator Trail is OVERTURNED/DISAGREED WITH since medical records concur with ODG recommendations for the procedure in attempt to manage severe chronic post surgical Cervical Spine pain despite continued diligent conservative care with activity modification, medications, Physical Therapy, and home exercise program, and clearance for the procedure by a recent Psychological Evaluation.
The "duration" of the procedure as noted by the previous Utilization Reviews, is not a specified criteria, but rather standard medical practice of adequate time in order to demonstrate benefit of the procedure with evidence of 50% pain relief and medication use, and/or functional improvement after a "temporary" trail to therefore necessitate permanent placement. Therefore, the request for Spinal Cord Stimulator Trail is found to be medically necessary.

PER ODG:

Conditionally Recommended CR

Recommended only for selected patients for specific conditions and in cases when less invasive procedures have failed or are contraindicated (see blue criteria to be met when considering use of a spinal cord stimulator). Spinal cord stimulators (SCS) are indicated for selected patients with Complex Regional Pain Syndrome (CRPS) Type I.

ODG Criteria

Indications for stimulator implantation:
• Complex Regional Pain Syndrome (CRPS) when all of the following are present:
(1) There has been limited response to non-interventional care;
(2) Psychological clearance indicates realistic expectations and clearance for the procedure;
(3) There is no current evidence of substance abuse issues;
(4) There are no contraindications to a trial;
(5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial.
• For use in failed back surgery syndrome (FBSS), see the Low Back Chapter.
• For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

Evidence Summary

More trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain. (Mailis-Gagnon-Cochrane, 2004) (BlueCross BlueShield, 2004). This supporting evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. (Sundaraj, 2005) 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. () CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. (#Taylor, 2006) SCS appears to be an effective therapy in the management of patients with CRPS. (Kemler, 2004) (Kemler, 2000) Recently published 5-year data from this study showed that change in pain intensity was not significantly different between the SCS plus PT group and the PT alone group, but in the subgroup analysis of implanted SCS patients, the change in pain intensity between the two groups approached statistical significance in favor of SCS, and 95% of patients with an implant would repeat the treatment for the same result. A thorough understanding of these results including the merits of intention-to-treat and as-treated forms of analysis as they

relate to this therapy (where trial stimulation may result in a large drop-out rate) should be undertaken prior to definitive conclusions being made. (Kemler, 2008) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined with physical therapy. (Harke, 2005) As batteries for both rechargeable and nonrechargeable systems are nearing end of life, there are both early replacement indicators and end of service notifications. Typical life may be 8-9 years for rechargeable batteries, but this depends on the unit. In addition, the physician programmer can be used to interrogate the implanted device and determine the estimated remaining battery life. (Restore, 2011)

Spinal cord stimulation (SCS)

Body system:
Low Back
Treatment type:
Electrical / Stimulators, Implants, Surgery
Related Topics:
See the Pain Chapter for *Indications for stimulator implantation*. See also Psychological evaluations (SCS) in the Mental Illness and Stress Chapter.

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

Conditionally Recommended CR

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated.

Evidence Summary

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 recent 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. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the 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 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) 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 and CRPS. (Taylor, 2005) (Taylor, 2006) SCS for treatment of chronic nonmalignant pain, including FBSS, has demonstrated a 74% long-term success rate (Kumar, 2006). SCS for treatment of failed back surgery syndrome (FBSS) reported better effectiveness compared to reoperation. (North, 2005) A cost utility analysis of SCS versus reoperation for FBSS based on this RCT concluded that SCS was less expensive and more effective than reoperation, and should be the initial therapy of choice. Should SCS fail, reoperation is unlikely to succeed. (North, 2007) Neuromodulation may be successfully applied in the treatment of visceral pain, a common form of pain when internal organs are damaged or injured, if more traditional analgesic treatments have been unsuccessful. (Kapural, 2006) (Prager, 2007) A recent RCT of 100 failed back surgery syndrome (FBSS) patients randomized to receive spinal cord stimulation plus conventional medical management (SCS

group) or conventional medical management alone (CMM group), found that 48% of SCS patients versus 9% of CMM patients achieved the primary outcome of 50% or more pain relief at 6 months. This study, funded by Medtronic, suggested that FBSS patients randomized to spinal cord stimulation had 9 times the odds of achieving the primary end point. (Kumar, 2007) According to the European Federation of Neurological Societies (EFNS), spinal cord stimulation (SCS) is efficacious in failed back surgery syndrome (FBSS). (Cruccu, 2007) *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 disc 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) (Frey, 2009) 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. 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) In this sample of workers' compensation recipients, the high procedure cost of SCS was not counterbalanced by lower costs of subsequent care, and SCS was not cost-effective. The benefits and potential cost savings reported in RCTs may not be replicated in workers' comp patients. (Hollingworth, 2011)

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)**