MEDICAL POLICY

SPINAL CORD STIMULATORS

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POLICY

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. A TRIAL IS REQUIRED BEFORE PERMANENT PLACEMENT. The following are the ONLY Indications for the Stimulator Cord Implantation:

- Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation and are not candidates for repeat surgery), when all of the following are present: Symptoms are primarily lower extremity radicular pain; there has been limited response to non-interventional care (e.g. neuroleptic agents, analgesics, injections, physical therapy, etc.);
- Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.)
- Post amputation pain (phantom limb pain), 68% success rate (Deer, 2001)
- Post herpetic neuralgia, 90% success rate (Deer, 2001)
- Spinal cord injury dyesthesias (pain in lower extremities associated with spinal cord injury)
- Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina. (Flotte, 2004)

Required pre-approval measures:

- Psychological clearance indicates realistic expectations and clearance for the procedure.
- No current evidence of substance abuse issues;
- No contraindications to a trial;
- Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial. Estimates are in the range of 40-60% success rate 5 years after surgery. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar due to potential complications and limited literature evidence.
Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. Although there is limited evidence in favor of Spinal Cord Stimulators (SCS) for Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type I, 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) See indications list below. See Complete list of SCS References. 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) 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. (Furlan-Cochrane, 2004) 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) 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) 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) and complex regional pain syndrome (CRPS) type I (level B recommendation). (Crucu, 2007) 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 chronic neuropathic pain lasting at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation. Recommended conditions include failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). (NICE, 2008) See also Psychological evaluations (SCS) in the Stress & Other Mental Conditions Chapter.

Battery Life for SCS: 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)

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) (Frey, 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)

PSYCHOLOGICAL EVALUATION MANDATE

Recommended pre intrathecal drug delivery systems (IDDS) and spinal cord stimulator (SCS) trial. The existing behavioral literature provides considerable support, including psychological assessments and treatments, for patients undergoing spinal cord stimulators or implanted medication pumps. (Van Dorsten, 2006) The following is a list of patients who are especially recommended for psychological evaluation pre-trial (Doleys): (a) Those who present with constant pain and report high overall levels of distress; (b) Patients’ who have a history of failure of conservative therapy; (c) Patient’s who have a history of failed surgery; (d) Patients who have significant psychological risk factors such as substance abuse, serious mood disorders, or serious personality disorders. Psychological predictors of success and/or failure of implantable treatment are still under research, and there is at least one study that has found psychological testing to be of modest value (although this was based on a cohort of patients that had been pre-screened by their surgeon). (North, 1996) However, the screening should be performed by a neutral independent psychologist or psychiatrist unaffiliated with treating physician/ spine surgeon to avoid bias. Current suggestions for the evaluation include the following three pronged approach (Prager, 2001) (Beltrutti, 2004) (Monsalve, 2000):

1. A clinical interview including the following: (a) Social history including education, psychosocial stress factors, childhood history (including history of abuse), family situation and work history; (b)
Comprehensive history including previous treatment (and response), psychological history; (c) History of substance abuse; (c) Attitudes towards pain and treatment, including painful behavior and moods of the patient; (e) Current emotional state; (f) Mental status exam; (g) Determination of motivation for recovery and return to work; (h) Issues related to implantation therapy. The interview should allow for measures of personality structure (both before and after the illness), environmental factors that influence pain, and personal strengths and internal resources.

(2) An interview with a significant other (if approved by the patient) to confirm findings, alert for other significant information, and allow for assessment of social support.

(3) Psychological testing. This supplements information provided in the clinical interview and, at the minimum, should evaluate personality style and coping ability. At least one test should contain validity scales. The current “gold standard” is the Minnesota Multiphasic Personality Inventory (MMPI, or a second version, the MMPI-2). MMPI scores of concern are findings of elevated neurotic triad scores (scales 1, 2, and 3; also defined as hypochondriasis [Hs], depression [D], and hysteria [Hy], or a Conversion V score [elevations of scales 1 and 3 at least 10 points above scale 2]). See Minnesota multiphasic personality inventory (MMPI). Other tests have included the Speilberger State-Trait Anxiety Inventory (STAI), Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Hospital Anxiety and Depression Scale (HAD), Millon Clinical Multiaxial Inventory (M-CMI-II), Symptom Checklist-90-R (SCL-90-R), Behavioral Analysis of Pain, Chronic Illness Problem Inventory (CIPI), McGill Pain Questionnaire (MPQ), Coping Strategies questionnaire (CSQ), and Pain Beliefs and Perception Inventory (PBPI).

Post-evaluation, three general categories of patients have been identified:

- **Group 1**: Patients with no contraindications for implantation

- **Group 2**: Patients who have a high likelihood of failure. Falling into this category does not mean that an implantable should not be used, but that contraindications should be treated prior to this intervention.

The following are current suggested exclusionary criteria for the use of an implantable pain treatment (Nelson, 1996): (a) Active psychosis; (b) Active suicidal ideation; (c) Active homicidal ideation; (d) Untreated or poorly treated major depression or major mood disturbance. Depression in and of itself in reaction to chronic pain does not disqualify a patient from implantable treatment, although moderately severe to severe depression should be treated prior to trial. Anxiety/panic disorder should also be stabilized; (e) Somatization disorder or other somatoform disorder involving multiple bodily complaints that are unexplained or exceed that could be explained by the physical exam; (f) Alcohol or drug dependence (including drug-seeking behavior and/or uncontrolled escalated use) See Opioids, red flags for addiction; (g) Lack of appropriate social support; (h) Neurobehavioral cognitive deficits that compromise reasoning, judgment and memory.

Other “red flags” include: a) unusual pain ratings (for example, the pain rating never changes from 9-10); b) unstable personality and interpersonal function; c) non-physiological signs reported on physical exam; d) unresolved compensation and litigation issues.

- **Group 3**: Patients who may require brief cognitive and/or behavioral intervention prior to the trial. These have also been referred to as “yellow flag” patients. The following are factors that have been found to increase the risk for a poor outcome: (a) Mild to moderate depression or anxiety; (b) Somatization disorder in the presence of medically explained pain; (c) Hypochondriasis if the focus is on something other than pain; (d) Mild to moderate impulsive or affective disorder; (e) Family distress/dysfunctional behavior; (f) Social distress/dysfunctional behavior; (g) Job distress/dysfunctional behavior. There is no good research as to what patients fall into this group. Treatment duration has been suggested according to severity of symptoms, with a general suggestion of approximately 6 sessions. Williams has suggested that this therapeutic intervention should include: a) education; b) skills training (training for a variety of cognitive and behavioral pain coping skills including relaxation training, activity pacing, pleasant activity scheduling, problem solving, and sleep hygiene); and c) an application phase to apply the above learned skills. (Doleys) (Beltrutti, 2004) (Gybelts, 1998) (Prager, 2001) (Williams, 2003) (Monsalve, 2000)
REFERENCES

1. Official Disability Guidelines 2013/ Pain Chapter