Medical Policy

Spinal Cord Stimulators for Pain
Effective Date: 05/01/2020    Revised Date: N/A
Responsible Department: Utilization Review    Reviewed Date: N/A

Purpose
The purpose of this document is to outline Workforce Safety & Insurance’s (WSI) treatment guidelines for spinal cord stimulators for pain.

Background
WSI adopted ODG by MCG, formerly Work Loss Data Institute’s Official Disability Guidelines (ODG) in July 2005, to use in the utilization review and claim management process. ODG by MCG provides independent, evidence-based medical treatment guidelines for conditions commonly associated with the workplace.

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Policy
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Appendix A
Treatment Guidelines – Spinal Cord stimulators (Continued)

The following guideline is an excerpt from ODG by MCG’s Spinal cord stimulators (SCS) section accessed on 04/23/2020.

**Recommendation**
Recommended as indicated below on a case-by-case basis as a third-line, last resort treatment for chronic neuropathic pain in post-spinal surgery patients, when ALL criteria are met. Not recommended for radiculopathy or axial back pain in patients who have not undergone spinal surgery, and not recommended to facilitate weaning pain medication. Newer SCS waveforms are considered investigational.

**ODG Criteria**

**Spinal cord stimulators (SCS) are recommended on a case-by-case basis for the following indications:**

- Failed back surgery with persistent leg pain that is determined to be related to nerve damage from the initial pathology and/or surgery as confirmed by exam and electrodiagnostic study.
- Neuropathic pain in post-spinal surgery patients in which there is no evidence of a nociceptive component to symptoms.

**SCS are not recommended for the following indications:**

- Not recommended for radiculopathy in patients who have not undergone spinal surgery.
- Not recommended for axial back pain in patients who have not undergone spinal surgery.
- Not recommended to facilitate weaning of pain medications. There is some suggestion that there is a trend towards lowered drug use with a SCS, but there are no randomized controlled trials with primary outcome of medication use to support this, and no guidance as to what patients would potentially be best treated for this indication. There is no guarantee that substantial pain relief will strongly correlate with lowering or actually stopping opioid use. In addition, higher doses of opioids pre-implant are associated with greater risk of failure and explanation.
- Not recommended to remove a current functional SCS (such as a traditional/tonic model) and replace with a newer waveform technology until there is documentation of a need for battery change or other medical necessity.
- Not recommended as a salvage treatment by replacing a traditional/tonic SCS that has failed with a newer waveform model, such as high frequency or burst.
- Not recommended to perform a repeat trial in patients who have failed a trial of SCS in the past.
- Not recommended for patients who will require future MRI evaluation for existing pathology.
- Not recommended for patients involved in litigation or in other circumstances involving secondary gain.

**Patient criteria for SCS:**

1. Patients should be informed that as many as 40% of patients may experience a permanent unit not providing pain relief even after a successful trial.

2. Patients should be informed that the rate of explanation (i.e., removal of the unit) is high, generally within 2 to 5 years, and the major reason for explanation is ineffective pain relief.
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Treatment Guidelines – Spinal Cord stimulators (Continued)

(3) Patients should be informed that tolerance to the analgesic effect may occur (i.e., the unit may lose its effectiveness). This has been documented in a randomized controlled trial at approximately 3 years in CRPS patients, and it has been documented in multiple retrospective studies in patients implanted for failed back surgery syndrome.

(4) Patients should be informed that there are currently no published data using randomized controlled trials longer than 36 months for newer waveform stimulators (e.g., high-frequency or burst).

(5) The treatment should not exceed the following parameters: 16 electrodes/contacts, 2 percutaneous leads, or 1 paddle lead for standard spinal cord stimulation.

(6) The pain source addressed with SCS treatment should be neuropathic as confirmed by exam and electrodiagnostic findings (where appropriate).

(7) Conservative therapy has been used and failed or judged unsuitable for at least a 6-month period (e.g., pharmacologic, psychologic, physical therapy, less invasive interventional therapy). A summary of this information should be documented with the request.

(8) A complete history and physical should be performed. The findings should be consistent between examiners. The exam should include documentation of all medical conditions (including those that are not work related in workers’ compensation patients). The exam should include evidence that peripheral neuropathies (such as those related to metabolic causes, alcohol, and hepatitis), and peripheral vascular disease have been evaluated for. All other causes of pain should be documented by history and exam findings.

(9) A complete drug list should be submitted, including for medications that are not work related in workers’ compensation patients.

(10) Laboratories should be obtained, including complete blood count, comprehensive metabolic profile, coagulation screening, and urinalysis. Diabetics may require a HgbA1c, and urine culture may be required.

(11) Pre-operative spinal MRI should be performed to search for an organic cause of ongoing pain.

(12) Additional imaging may be required in the thoracic region to assess for critical stenosis or other anatomical abnormalities prior to implant.

(13) Completion of a neuropathic pain questionnaire is recommended. Examples include the Neuropathic Pain Questionnaire, ID Pain and PainDETECT.

(14) A psychological evaluation should be performed by an independent psychologist with no conflict of interest. A one-on-one evaluation is recommended, with inclusion of psychometric testing (such as the MMPI-2RF or MPI). It is recommended that results of this testing be provided. The procedure is not recommended in patients with major psychiatric disease and/or psychosis. Caution should be used in patients with documented depression, mood disorder, and/or anxiety, as these are considered risk factors for failure. The procedure should not be undertaken in any patient with a diagnosis of somatic symptom disorder, with the knowledge that this can be present in up to 60% of patients who present in specialty pain clinics.
(15) A substance use disorder screen should be part of the psychological evaluation. Patients with evidence of substance-use disorder or frank drug habituation should not be implanted until these conditions are addressed. Presence of ongoing substance use pathology (including that related to prescription drugs) may be a permanent reason to deny this treatment.

(16) Patients who are unable to cognitively participate in an SCS trial, implant and post care should not be implanted.

(17) Any local or systemic infection should be addressed. This may include testing such as urinalysis and culture if indicated.

(18) Compatibility with other implantable devices, such as cardiac pacemakers and defibrillators, should be verified.

(19) After the above criteria have been fulfilled and SCS is considered medically appropriate, a trial is required. This usually occurs from 3-7 days. Pain and function should improve by ≥ 50%, with documentation provided. Documentation should also include whether any changes were made to pain medications.

**Evidence Summary**

Spinal cord stimulators (SCS) are seen as a therapy for patients suffering primarily from neuropathic pain for which there is no alternative therapy. Conventional (tonic) SCS has been characterized by limited success rates (generally about 50%) and reports of decline in efficacy over time. Newer advances in technology have produced multiple alternatives to the conventional SCS treatment. Both conventional and newer technology is accompanied by lack of scientific understanding of mechanism, including how this therapy modulates physiological effect and central pain processing. There has been criticism that without a complete understanding of the technology involved in SCS treatment, patients may be subjected to unnecessary health and financial burden. It has also been suggested that industry-sponsored research may create conflicts of interest and influence objectivity. (Duy, 2018) Further unanswered questions include (1) how to best select patient suitable for treatment and (2) how the treatment affects outcomes other than pain (e.g., patient preference, function, return to work, and quality-of-life outcomes). Questions about long-term efficacy for all modalities remain a problem (particularly because studies with follow-up longer than 36 months are not available for the new waveforms). There is also suggestion that placebo effect may confound scientific studies to some degree. These problems are all further complicated by the heterogeneity and lack of medical understanding about the two major conditions generally addressed with this treatment: failed back surgery syndrome and CRPS. Due to the limited amount of research to support this technology and the large gaps in our understanding (as noted above), limited approval is recommended. (Lempka, 2018) (Amirdelfan, 2017) (Provenzano, 2017)
Appendix B
Treatment Guidelines – Psychological evaluations, IDDS & SCS

The following guideline is an excerpt from ODG by MCG’s Psychological evaluations, IDDS & SCS (intrathecal drug delivery systems & spinal cord stimulators) section accessed on 04/22/2020.

**Recommendation**
Recommended prior to a trial for an intrathecal drug delivery system (IDDS) or spinal cord stimulator (SCS) as per the criteria below.

**Criteria for Psychological evaluations, IDDS and SCS (intracathedral drug delivery systems and spinal cord stimulators):**

1. A one-on-one psychological evaluation is required by an independent unbiased psychologist.
2. Psychological testing should be included. At least one test should evaluate personality style and coping ability. Examples include the MMPI-2, MMPI-2-RF, and Millon Clinical Multiaxial Inventory. The actual results should be included.
3. At least one test should contain validity scales.
4. These procedures are not recommended in patients with major psychiatric disease and/or psychosis.
5. Caution should be used in patients with documented depression, mood disorder, and/or anxiety, as these comorbidies are considered risk factors for failure.
6. Extreme caution should be used in dealing with patients with personality disorders or untreated posttraumatic stress disorder.
7. The procedure should not be undertaken in any patient with a diagnosis of somatic symptom disorder, keeping in mind that this condition can be present in up to 60% of patients treated at specialty pain clinics.
8. A substance use disorder screen should be part of the psychological evaluation. Patients with evidence of substance-use disorder or frank drug habituation should not be implanted until these conditions are addressed. Presence of ongoing substance use pathology (including that related to prescription drugs) may be a permanent reason to deny this treatment.
9. Personal expectations should be addressed, including clarification that a patient should not expect > 50% reduction in pain. (Fama, 2016)

**Recommendations for components of the psychological evaluation:**

1. A clinical interview that allows for measures of personality structure (both before and after the illness), environmental factors that influence pain, and personal strengths and internal resources. The clinical interview should include 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
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Treatment Guidelines – Psychological evaluations, IDDS & SCS

(c) History of substance abuse
(d) 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

(2) A review of medical records.

(3) Psychological testing. This testing supplements information provided in the clinical interview and, at minimum, should evaluate personality style and coping ability. At least one test should contain validity scales, with the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), a test for personality and psychopathology profile, commonly recommended. The Minnesota Multiphasic Personality Inventory-2-RF (MMPI-2-RF) has also been studied, particularly using the scales of emotional dysfunction (particularly Demoralization and Dysfunctional Negative Emotions), somatic/cognitive dysfunction, and interpersonal functioning. (Block, 2017) (Marek, 2020) Other tests in this category include the Millon Clinical Multiaxial Inventor (MILLON-IV) and the Life Orientation Test-Revised (LOT-R). Other testing can include those for pain assessment and beliefs, quality of life and disability, anxiety and depression, and coping.

(4) 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.

Evidence Summary

Existing behavioral literature provides considerable support for use of psychological assessments and treatments for patients undergoing spinal cord stimulators or implanted medication pumps, although there is no consensus in terms of specific psychological screening. Formal psychometric testing is recommended as a component of psychological screening in order to generate a clear and justifiable prognosis and potential treatment plan. Screening should be performed by a neutral independent psychologist or psychiatrist unaffiliated with the treating physician or spine surgeon to avoid bias. (Blackburn, 2016) (Van Dorsten, 2006) (De Andrés, 2020) (Celestin, 2009) (Sparkes, 2010) (Wolter, 2013) (Campbell, 2013)

Three general categories of patients can be identified based on psychological evaluation. Group 1 includes patients with no contraindications for implantation. Group 2 includes patients who may require brief cognitive and/or behavioral intervention prior to the trial. These have also been referred to as “yellow flag” patients. There is no good research regarding who falls into this group, but 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; and (g) job distress/dysfunctional behavior. 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. (Williams, 2003) (Fama, 2016)
Group 3 includes patients who have a high likelihood of failure. Falling into this category does not mean that an implantable device should not be used but that contraindications should be treated prior to the intervention. Suggested exclusionary criteria for the use of an implantable pain treatment include the following: (a) active psychosis; (b) active suicidal ideation; (c) active homicidal ideation; (d) somatization disorder or other somatoform disorder involving multiple bodily complaints that are unexplained or exceed what could be explained by the physical exam; (e) alcohol or drug dependence (including drug-seeking behavior and/or uncontrolled escalated use); (f) lack of appropriate social support; and (g) neurobehavioral cognitive deficits that compromise reasoning, judgment, and memory. (Nelson, 1996) Untreated or poorly treated major depression, major mood disturbance, or anxiety may also fall into this category. 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; or d) unresolved compensation and litigation issues. (Celestin, 2009)

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