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RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord

MCG Health
Ambulatory Care
27th Edition

AUTH: RMHP-A-024327 (AC)

Link to Codes

Clinical Indications for Procedure

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

- For members with **PRIME (Medicaid), CHP+ or Individual and Family Plan (IFP) Commercial** coverage, implanted electrical stimulator, spinal cord, may be indicated when **ALL** of the following are present(1) :
  - Chronic neuropathic or ischemic pain, including **1 or more** of the following(2)(3)(4)(5)(6):
    - Complex regional pain syndrome (previously referred to as reflex sympathetic dystrophy)(7)
    - Failed back surgery syndrome [A] (9)
    - Lower extremity pain at rest due to critical limb ischemia(10)
  - Failed conservative management, including **1 or more** of the following(3)(11):
    - For limb ischemia, failed surgical or endovascular revascularization, or inoperable vascular disease
    - For neuropathic pain, stellate ganglion or lumbar sympathetic block
    - Pharmacotherapy [B] (13)
    - Physical therapy(13)
    - Psychotherapy or cognitive behavioral therapy
  - Favorable psychological evaluation, absence of untreated psychiatric comorbidity, or current treatment in multidisciplinary pain management program(14)(15)
  - Improvement in pain with percutaneous test stimulation of spinal cord(16)(17)
  - Patient capable of operating stimulating device
  - No coagulopathy, anticoagulant or antiplatelet therapy, or thrombocytopenia (ie, platelet count of less than 75,000/mm^3 (75 x10^9/L))(15)(18)(19)

    - No current or chronic infection(19)
- For members with **RMHP Medicare (CareAdvantage or DSNP Dual Special Needs Plan)** coverage, Dorsal Column (Spinal Cord) Neurostimulation / Implanted electrical stimulator, spinal cord may be indicated when **ALL** of the following
    - late or last resort: The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
    - other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
    - completion of careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);
    - All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy screening requirements must be available
    - successful trial - Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Alternatives to Procedure

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

- Alternatives include:
    - For complex regional pain syndrome(20)(21):
        - Cognitive behavioral therapy
        - Electrical nerve stimulation. See Electrical Nerve Stimulation, Transcutaneous (TENS) AC for further information.
        - Lumbar sympathetic block. See Nerve Block or Neurolysis, Lumbar Sympathetic AC for further information.
        - Pharmacotherapy, including possible intrathecal medication.(22)(23) See Intrathecal Pump Implantation AC for further information.
        - Physical therapy modalities
        - Stellate ganglion block. See Nerve Block, Stellate Ganglion AC for further information.
    - For failed back surgery syndrome:
        - Cognitive behavioral therapy
        - Epidural corticosteroid injection. See Epidural Corticosteroid Injection AC for further information.
        - Pharmacotherapy, including possible spinal opiates.(23) See Intrathecal Pump Implantation AC for further information.
        - Physical therapy. See Spine Soft Tissue Dysfunction Rehabilitation AC for further information.
        - Spinal manipulation therapy. See Spinal Manipulation Therapy (SMT), Chiropractic and Other AC for further information.

Evidence Summary

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

Background

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

Spinal cord stimulation involves implanting a spinal cord stimulator lead into the epidural space either percutaneously or by surgical laminectomy or laminotomy. Electric impulses are generated by a pulse generator that is implanted subcutaneously. These electric impulses generate stimuli that mask sensations of pain.(24) **(EG 2)** Prior to implantation of a permanent system, patients must undergo test screening with a percutaneous stimulation system to ensure that paresthesia is achieved.(25) **(EG 2)**

Criteria

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

For chronic neuropathic or ischemic pain, A specialty society guideline recommended spinal cord stimulation for patients with failed back surgery syndrome and complex regional pain syndrome (previously referred to as reflex sympathetic dystrophy) who have failed conservative evidence-based interventions and are not candidates for corrective surgery.(2) **(EG 2)** A systematic review of 6 studies (including 5 randomized controlled trials) reported that spinal cord stimulation was effective for reducing chronic pain secondary to failed back surgery syndrome.(26) **(EG 1)** A systematic review and meta-analysis of 8 placebo-controlled randomized trials (185 patients) evaluating spinal cord stimulation for the management of neuropathic pain (including failed back surgery syndrome and complex regional pain syndrome) found that spinal cord stimulation was associated with a reduction in pain intensity measured by visual analog scale scores compared with control. However, the authors noted that the small sample sizes, variable use of spinal cord stimulators, and differing control setups in the included studies may have limited the analysis.(27) **(EG 1)** A specialty society guideline evaluating the appropriate use of spinal cord stimulation for the treatment of chronic pain and ischemic disease supports the use of spinal cord stimulation for the treatment of failed back surgery syndrome and complex regional pain syndrome in patients with the following characteristics: chronic neuropathic pain, favorable psychological evaluation, improvement in symptoms with percutaneous test stimulation prior to device implantation, and absence of contraindications such as coagulopathy or infection.(24) **(EG 2)** A systematic review reported that psychological factors such as somatization, depression, anxiety, and poor coping skills are associated with poor outcome for surgical interventions, including spinal cord stimulation.(28) **(EG 2)** An observational study of 402 patients treated with a spinal cord stimulator for neuropathic pain (primary implantation or replacement implantation) reported a significant reduction in pain intensity at 2 years (defined as a 50% or greater reduction in pain intensity from baseline); however, only 77% of patients completed the 2-year follow-up.(29) **(EG 2)** A systematic review identified 6 studies (444 patients total) assessing spinal cord stimulation for end-stage peripheral vascular disease in the lower extremities; the review found that active and control groups achieved significant pain relief, and patients in the spinal cord stimulation group required significantly fewer analgesics.(30) **(EG 1)**

Inconclusive or Non-Supportive Evidence

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

For angina pectoris (refractory), A systematic review identified 7 randomized controlled trials with a total of 270 patients and concluded that spinal cord stimulation had efficacy and safety similar to percutaneous myocardial laser revascularization, making it a potential alternative treatment; however, the review stated that further high-quality trials were needed before stimulation could be accepted as a routine treatment for this condition.(31) **(EG 1)** A systematic review (538 patients total) concluded that spinal cord stimulation decreases anginal attacks and can improve functional status. Of note was that in the 3 largest studies, 104 patients had 5-year follow-up, 104 patients had 2-year follow-up, and 68 patients had 1-year follow-up.(32) **(EG 2)** A study of 153 patients comparing enhanced external counterpulsation with spinal cord stimulation for refractory angina reported that, at 12-month follow-up, although both treatments reduced angina, enhanced external counterpulsation was slightly more effective than spinal cord stimulation.(33) **(EG 2)**

For cancer-related pain (refractory), A systematic review concluded that current evidence is insufficient to establish the efficacy of spinal cord stimulation for refractory cancer-related pain.(34) **(EG 1)** A specialty society practice guideline states that spinal cord stimulation may be an option in patients with refractory cancer pain; however, the authors note the clinical evidence is limited to case reports and case series.(35) **(EG 2)**

For chronic systolic heart failure, A randomized, parallel, single-blind, controlled trial including 66 patients with New York Heart Association functional class III systolic heart failure who were implanted with a spinal cord stimulator found, at 6-month follow-up, that there was no significant difference in left ventricular end-systolic volume index, freedom from hospitalization for heart failure or death, or change in New York Heart Association functional classification between the active stimulation group and control group.(36) **(EG 1)**

For chronic visceral abdominal pain, A systematic review of 7 studies (31 patients) evaluating spinal cord stimulation for the management of pain with chronic pancreatitis found that treatment with spinal cord stimulation was associated with a median 61% reduction in visual analog scale pain scores and a median 69% reduction in opioid use at the end of the follow-up period. However, the authors noted that the small sample sizes and lack of randomized controlled trials limited the analysis, and they recommended additional trials to assess for efficacy.(37) **(EG 1)** A national survey of pain management physicians was conducted due to a lack of consensus regarding patient selection and appropriate lead placement of spinal cord stimulation for this condition. Twenty-three physicians who treated 70 patients responded to the survey; the most frequent indications for treatment were pain due to chronic pancreatitis, postoperative abdominal adhesions, and gastroparesis. At a mean follow-up of 84 weeks for the 66 patients who received permanent implantation, spinal cord stimulation was associated with a reduction in pain scores and opioid use. The authors acknowledged that selection bias was a study weakness (ie, interventional pain management physicians with negative results may not have responded to the survey).(38) **(EG 2)**

For diabetic neuropathy-related pain (refractory), A randomized open-label trial of 216 patients with medication-refractory painful diabetic neuropathy of the lower limb compared treatment with conventional medical management with and without concomitant spinal cord stimulation and found, at 3-month follow-up, that spinal cord stimulation was associated with a greater percentage of patients achieving at least 50% pain relief without worsening baseline neurologic deficits compared with conventional medical management alone (79% and 5% in the stimulation and medical therapy groups, respectively). However, the authors noted that the unblinded nature of the trial may have resulted in a significant placebo effect, and long-term follow-up is planned. Patients with an HbA1c greater than 10% (86 mmol/mol), body mass index greater than 45, or opioid requirement of greater than 120 mg/day morphine equivalents were excluded from the study, which may affect the study's generalizability.(39) **(EG 1)** A follow-up of this study found that by 6 months, 81% of patients originally assigned to conventional medical management had crossed over to the spinal cord stimulation treatment group due to persistent symptoms of painful diabetic neuropathy. At 6-month and 12-month follow-up, patients in the spinal cord stimulation group (in both the original treatment group and the crossover group) achieved at least a 70% reduction in patient-reported lower limb pain; more than 60% of patients in the spinal cord stimulation group had improved sensory function. Additional follow-up is planned through 24 months.(40) **(EG 1)** A systematic review and meta-analysis of 2 randomized controlled trials (93 patients) evaluating the efficacy of spinal cord stimulation for the management of painful diabetic neuropathy found, at 6-month follow-up, that spinal cord stimulation was associated with a significant reduction in pain intensity and a greater proportion of patients achieving at least a 50% reduction in pain as compared with best medical therapy. However, the authors recommended future trials due to the small sample size and high risk of bias of the included studies.(41) **(EG 1)**

For postherpetic neuralgia, A systematic review evaluating interventional treatments for postherpetic neuralgia included 6 case series (94 patients) of spinal cord stimulation and found that some patients benefit; further study was recommended to evaluate which subset of patients were most likely to respond to treatment.(42) **(EG 1)** A randomized controlled trial of 63 patients with herpes zoster-related pain (duration of 1 to 6 months) treated with either spinal cord stimulation or pulsed radiofrequency found that both groups experienced a decrease in numeric rating scale pain scores with no difference noted between the groups.(43) **(EG 1)**

Policy History

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

History Summary: July 2017 RMHP adopted MCG guidance with CMS LCD/LCA for Medicare. Annual reviews thereafter and updates as needed. 11/3/2023 Annual review and update to 27th edition MCG with NCD guidance added, as LCD/LCA retired by Novitas.

References

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

The Center for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7) Publication Number 100-3, Manual Section Number 160.7, effective date 8/7/1995, reviewed 11/3/2023. (Note: LCD L35450 and LCA A57023 were retired by Novitas 7/13/2023.)

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Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

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Footnotes

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

[A] Failed back surgery syndrome is described as persistent low back pain, either with or without lumbosacral radiculopathy, after one or more spine surgeries.(8) [A in Context Link 1]

[B] There is some evidence to support the short-term benefit of opioids for mild to moderate pain, but the evidence for improvement in function is inconsistent. Given that chronic opioid therapy for noncancer pain often begins with acute opioid prescriptions, clinicians should provide the lowest effective dose for the shortest duration necessary (eg, 2 to 3 days) to alleviate pain when giving prescriptions for acute pain; limiting the duration of opioid therapy can minimize the need to taper to prevent withdrawal symptoms at the end of the course of opioids and limit unused opioids.(12) [B in Context Link 1]

Codes

Return to top of *RMHP Spinal Cord Stimulator (SCS) - Implanted Electrical Stimulator, Spinal Cord - AC*

CPT® : 62321, 62323, 62325, 63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688

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