Spinal Cord Stimulators - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 2
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Important Notices

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Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System
Guideline Name: Spinal Cord Stimulators (Single Service)

Literature review current through: 4/30/2024
Document last updated: 4/30/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Spinal Cord Stimulators

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Spinal cord stimulators (SCS) are a therapeutic technique that involves the placement of an implantable device that delivers electrical impulses to the spinal cord to alleviate chronic pain.[1-5] Before the permanent SCS placement, a trial must be conducted to assess if the patient will respond adequately to the SCS. SCS has been used successfully to manage various chronic pain conditions when other treatments have failed.[1]
- **Exclusions:** Active systemic infection, Coagulopathy or bleeding diathesis, active use of antiplatelet or anticoagulant medications, pregnancy, and allergy to implant materials. SCS is not appropriate for all patients with chronic pain, and careful patient selection is necessary to achieve optimal outcomes.[1]

Medical Necessity Criteria

Indications

➔ **Spinal cord stimulators** are considered appropriate if **ANY** of the following is **TRUE**:

- ◆ A **spinal cord stimulator trial** is appropriate when **ALL** of the following are **TRUE**:
  - Failure of conservative management for greater than 6 months within the last 12 months including **ALL** of the following:
    - Oral steroids, anti-inflammatory medications, analgesics, or neuropathic pain medications; **AND**
    - Physical therapy; **AND**
    - **ANY** of the following:
      - ◆ Interventional spinal injection if medically appropriate, including **ANY** of the following:
        - Epidural steroid injections; **OR**
        - Facet blocks; **OR**
        - Facet joint denervation; **OR**
        - Medial branch blocks; **OR**
        - Lumbar sympathetic blocks; **OR**

        - Interventional spinal injection (Epidural steroid injection, facet block, etc.) is contraindicated; **OR**
        - For diabetic neuropathy interventional spinal injection is not necessary; **AND**
- Duration of chronic pain intractable pain (pain level greater than or equal to 6 out of 10) for at least 6 months; **AND**
- Documentation of pain causing moderate to severe functional disability as documented by a Oswestry Disability Index (ODI)[6] score greater than or equal to 21%; **AND**
- Spinal cord stimulator is considered a last resort after exhausting other treatments for chronic, intractable pain; **AND**
- Pain-focused psychological evaluation and clearance has been performed within the last 12 months to determine if the patient is a suitable candidate; **AND**
- Member does not have any untreated existing substance use disorder(s); **AND**
- The patient has **ANY** of the following conditions:
    - **Complex regional pain syndrome (CRPS)** also known as reflex sympathetic dystrophy (RSD) as evidenced by **ALL** of the following:
        - Continued, ongoing pain, disproportionate to any inciting event (e.g., surgery, trauma); **AND**
        - **ANY** of the following sensory symptoms:
            - Allodynia; **OR**
            - Hyperesthesia; **AND**
        - **ANY** of the following vasomotor symptoms:
            - Skin color asymmetry; **OR**
            - Skin color changes; **OR**
            - Temperature asymmetry; **AND**
        - **ANY** of the following sudomotor or edema symptoms:
            - Edema; **OR**
            - Sweating asymmetry; **OR**
            - Sweating changes; **AND**
        - **ANY** of the following motor or trophic symptoms:
            - Decreased range of motion (ROM); **OR**
            - Motor dysfunction (weakness, tremor, dystonia); **OR**
            - Trophic changes (hair, nails, skin); **AND**
        - **TWO or more** of the following physical exam findings:

- Sensory (e.g., hyperalgesia [to pinprick], allodynia [to light touch]); **OR**
- Vasomotor (e.g., temperature asymmetry, skin color changes, skin color asymmetry); **OR**
- Sudomotor or edema (e.g., edema, sweating asymmetry, sweating changes); **OR**
- Motor or trophic (e.g., decreased ROM, motor dysfunction [weakness, tremor, dystonia], trophic changes [hair, nails, skin]); **AND**

◆ Failure of adequate relief with a lumbar sympathetic nerve block; **AND**

◆ **ANY** of the following is **TRUE**:

- Failure of at least 3 month trial of at least 2 neuropathic medications (e.g., gabapentin, Pregabalin, Duloxetine, amitriptyline, nortriptyline, etc.); **OR**
- Use of such medications is contraindicated; **OR**

○ **Failed Back Surgery Syndrome (FBSS)** with **ALL** of the following:

◆ Persistent or recurrent pain following spinal surgery (e.g., post-laminectomy); **AND**

◆ The patient is not a candidate for further surgical intervention; **OR**

○ **Painful lower limb diabetic neuropathy** with **ALL** of the following:

◆ Documentation from primary care physician or endocrinologist that patients glucose control has been optimized, along with documentation of an HbA1c of equal or less than 9; **AND**

◆ **ANY** of the following is **TRUE**:

- Failure of at least 3 month trial of at least 2 neuropathic medications (e.g., gabapentin, Pregabalin, Duloxetine, amitriptyline, nortriptyline, etc.); **OR**
- Use of such medications is contraindicated; **OR**

◆ A **permanent spinal cord stimulator** is appropriate if the patient has had a successful spinal cord stimulator trial, as indicated by **ALL** of the following[7]:

- Temporary spinal cord stimulator trial of at least 3 days trial; **AND**

- Demonstration of at least 50% reduction in pain relief during the trial; **AND**
- Improvement in **ANY** of the following:
    - Ability to perform daily activities; **OR**
    - Documented improvement in the patient's quality of life; **OR**
    - Functional disability scale; **OR**
    - Increased mobility; **OR**
    - Reduced use of pain medications.

Non-Indications

➔ **Spinal Cord Stimulators** may not be considered appropriate if **ANY** of the following is **TRUE**[7]:

- Active substance abuse issues; **OR**
- Active systemic infection; **OR**
- Active use of antiplatelet or anticoagulant medications; **OR**
- Allergy to implant materials; **OR**
- Coagulopathy or bleeding diathesis; **OR**
- Dorsal root ganglion (DRG) stimulation as there is insufficient evidence to support use for all other conditions[8]; **OR**
- DRG stimulator for all conditions except for adult patients with Complex Regional Pain Syndrome (CRPS) types I and II as it is FDA approved only for the management of moderate to severe chronic intractable pain of the lower limbs[9]; **OR**
- More than 2 SCS trials per anatomic spinal region per patient per lifetime is not considered reasonable and necessary[8]; **OR**
- The patient has other implanted programmable devices (e.g., existing spinal cord stimulator, cardiac pacemakers, defibrillators), unless there is a plan to manage the device(s) as recommended by the manufacturer; **OR**
- Pregnancy; **OR**
- A repeat trial after initial trial failure unless extenuating circumstances were present that contributed to trial failure[8]; **OR**
- Replacement or upgrade when **ANY** of the following is **TRUE**:
    - The SCS is functioning but is not MRI compatible to one that is MRI compatible; **OR**
    - The SCS is functioning and newer technology is required (including but not limited to BurstDR, high-frequency SCS, closed loop SCS, etc.); **OR**
    - Lead and electrode replacement as they are not generally required at the time of a generator replacement due to the end of battery life; **OR**
- Trials or implants performed by non-physicians; **OR**

- Untreated psychiatric conditions (e.g., severe anxiety and depression, bipolar disorder, personality disorders) that may impact the patient's ability to comply with postoperative instructions or may be at an increased risk for complications due to psychiatric instability.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

CPT/HCPCS Code	Code Description
63650	Implantation of neurostimulator electrode array, epidural (may be used for revision or replacement of leads).
63655	Laminectomy for implantation of electrode array, plate/paddle, epidural
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of SCS pulse generator or receiver.
63688	Revision including replacement, removal, or repositioning of an SCS pulse generator or receiver.
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging

	system
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8682	Implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

Medical Evidence

Petersen et al. (2023) conducted a prospective, multicenter, randomized controlled trial (RCT) to assess the effectiveness of spinal cord stimulation (SCS) at a frequency of 10 kHz in managing persistent painful diabetic neuropathy (PDN) that has not responded to conventional treatments. The trial included 216 patients with refractory PDN; researchers compared conventional medical management (CMM) alone with a combination of CMM and 10 kHz SCS. At 6-month follow-up, patients with inadequate pain relief were given the option to begin the other treatment. The 142 patients with the 10 kHz SCS system were followed for 24 months. Results showed that at 24 months, 10 kHz SCS reduced pain by an average of 79.9% compared to baseline, with 90.1% experiencing at least 50% pain relief. Participants also saw significant improvements in quality of life and sleep, with 65.7% demonstrating clinically meaningful neurological improvement. The study supports 10 kHz SCS for lasting pain relief and notable improvements in quality of life, sleep, and neurological function over 24 months.[10]

Kapural et al. (2023) performed a prospective, multicenter, randomized, single-masked feasibility study to evaluate the safety and efficacy of a novel charge-distributed multiphase stimulation approach throughout an extended trial of SCS. The study included patients with chronic low back or leg pain (or both) who underwent a successful commercial SCS trial. Patients were randomized into two groups receiving different multiphase SCS therapies, with varying frequency ranges, over an 11-to-12-day period. Results showed significant reductions in pain intensity for both multiphase therapies compared to baseline. There was no significant difference in pain reduction was noted between the two multiphase therapies. In conclusion, multiphase SCS effectively reduced pain in participants with chronic low back or leg pain, with no unexpected device-related adverse events. Future research should focus on assessing the long-term effectiveness of multiphase stimulation.[11]

Zuidema et al. (2023) conducted a prospective cohort RCT to assess the enduring impacts of SCS on patients with painful diabetic polyneuropathy (PDPN). The study is an eight-to-ten-year follow-up of a previous trial on SCS for PDPN that focused on a subgroup of 19 patients who still used SCS treatment after eight years. The study notes that pain intensity during the day and night significantly decreased compared to baseline. More than 50% of patients experienced a pain reduction of over 30%. However, there were no significant differences in secondary outcomes such as quality of life, depression, and sleep quality. The conclusion suggests that SCS can remain an effective long-term treatment for reducing pain intensity in some patients with PDPN who still have the device implanted after eight years.[12]

References

1. Kapural L, Peterson E, Provenzano DA, et al. Clinical evidence for spinal cord stimulation for Failed Back Surgery Syndrome (FBSS): Systematic review. *Spine (Phila Pa 1976)*. 2017 Jul 15:42 Suppl 14:S61-S66. doi: 10.1097/BRS.0000000000002213. PMID: 28441313.
2. Simpson EL, Duenas A, Holmes MW, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess*. 2009 Mar;13(17):iii, ix-x, 1-154. doi: 10.3310/hta13170. PMID: 19331797.
3. Kumar K, Rizvi S. Cost-effectiveness of spinal cord stimulation therapy in management of chronic pain. *Pain Med*. 2013 Nov;14(11):1631-49. doi: 10.1111/pme.12146. PMID: 23710759.
4. Van Buyten JP, Linderoth B. The failed back surgery syndrome: definition and therapeutic algorithms—an update. *Eur J Pain Suppl*. 2010; 4:273–286. doi: https://doi.org/10.1016/j.eujps.2010.09.006.
5. Kapural L, Yu C, Doust MW, et al. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain the SENZA-RCT randomized controlled trial. *Anesthesiology*. 2015 Oct;123(4):851-60. doi: 10.1097/ALN.0000000000000774. PMID: 26218762.
6. Vianin M. Psychometric properties and clinical usefulness of the Oswestry Disability Index. *J Chiropr Med*. 2008 Dec;7(4):161-3. doi: 10.1016/j.jcm.2008.07.001. PMID: 19646379; PMCID: PMC2697602.
7. Boswell MV, Trescot AM, Datta S, et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician*. 2007 Jan;10(1):7-111. PMID: 17256025.
8. Centers for Medicare and Medicaid Services (CMS). Local coverage determination (LCD) - spinal cord stimulators for chronic pain (L35136). Revision Effective Date December 1, 2019. Accessed April 24, 2024. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35136.
9. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Dorsal root ganglion stimulator for pain relief (P150004). Published February 11, 2016. Accessed April 24, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150004b.pdf.
10. Petersen EA, Stauss TG, Scowcroft JA, et al. Long-term efficacy of high-frequency (10 kHz) spinal cord stimulation for the treatment of painful diabetic neuropathy: 24-month results of a randomized controlled trial. *Diabetes Res Clin Pract.* 2023 Sep:203:110865. doi: 10.1016/j.diabres.2023.110865. PMID: 37536514; PMCID: PMC10801706.
11. Kapural L, Patterson DG, Li S, et al. Multiphase spinal cord stimulation in participants with chronic back or leg pain: Results of the BENEFIT-02

randomized clinical trial. *Neuromodulation*. 2023 Oct;26(7):1400-1411. doi: 10.1016/j.neurom.2023.05.006. PMID: 37589641.
12. Zuidema X, van Daal E, van Geel I, et al. Long-term evaluation of spinal cord stimulation in patients with painful diabetic polyneuropathy: An eight-to-ten-year prospective cohort study. *Neuromodulation*. 2023 Jul;26(5):1074-1080. doi: 10.1016/j.neurom.2022.12.003. PMID: 36587999.

Clinical Guideline Revision History/Information

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