Cohere Medical Policy - Spinal Cord Stimulators

Clinical Guidelines for Medical Necessity Review

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Medical Necessity Criteria

Service: Spinal Cord Stimulators

Recommended Clinical Approach

A spinal cord stimulator (SCS) is an implantable device that delivers electrical impulses to the spinal cord to alleviate chronic pain. Before the permanent SCS placement, a trial must be conducted to assess if the patient will respond adequately to the SCS. The device is not appropriate for all patients with chronic pain, and careful patient selection is necessary to achieve optimal outcomes. Dorsal Root Ganglion (DRG) stimulation is done via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II. An SCS is considered a late or last resort after exhausting other treatments for chronic, intractable pain.[1-5]

Medical Necessity Criteria

Indications

- ➔ A **spinal cord stimulator (SCS)** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ An **SCS trial** is appropriate when **ALL** of the following are **TRUE**:
    - Pain has been present for greater than or equal to 6 months; **AND**
    - Chronic moderate to severe intractable pain as measured on a pain scale (e.g. NRS or VAS >/=4/10); **AND**
    - Documentation of pain causing moderate to severe functional disability as measured on a disability scale (e.g. Oswestry Disability Index [ODI][6] score greater than or equal to 21%, other disability indexes are acceptable); **AND**
    - Pain-focused psychological evaluation and clearance have been performed within the last 12 months to determine if the patient is a suitable candidate; **AND**
    - The patient has **ANY** of the following conditions:
      - Complex regional pain syndrome (CRPS), also known as reflex sympathetic dystrophy (RSD), as diagnosed by **ALL** of the following, as per Budapest criteria[7]:
        - ◆ Continued, ongoing pain, disproportionate to any inciting event (e.g., surgery, trauma); **AND**

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- Must report a symptom in **AT LEAST THREE** of the following categories:
  - Sensory: reports of hyperesthesia and/or allodynia; **OR**
  - Vasomotor: reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry; **OR**
  - Sudomotor/edema: reports of edema and/or sweating changes and/or sweating asymmetry; **OR**
  - Motor/trophic: reports of decreased range of motion and/or motor; **OR** dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin); **AND**
- The patient has signs of **AT LEAST TWO** of the following categories at the time of evaluation:
  - 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 conservative management for greater than 3 months within the last 12 months, including **ALL** of the following, if medically appropriate and not contraindicated:
  - Prescription pain medications(e.g. anti-inflammatory medications, non-opioid analgesics, opioid medications, etc.); **AND**
  - Failure of at least a 3-month trial of at least 2 neuropathic medications (e.g., gabapentin, pregabalin, duloxetine, amitriptyline, nortriptyline, etc.); **AND**
  - Physical therapy, including a home exercise program; **AND**

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        - Failure of adequate relief with interventional pain procedure(e.g. sympathetic nerve block); **OR**
    - Failed back surgery syndrome (FBSS), post-laminectomy syndrome with **ALL** of the following:
        - Failure of conservative management for greater than 3 months within the last 12 months, including **ALL** of the following, if medically appropriate and not contraindicated:
            - Prescription pain medications(e.g. anti-inflammatory medications, non-opioid analgesics, opioid medications, etc.); **AND**
            - Failed trial of at least 2 neuropathic medications (e.g., gabapentin, pregabalin, duloxetine, amitriptyline, nortriptyline, etc.); **AND**
            - Physical therapy, including a home exercise program; **AND**
            - Failure of adequate relief with interventional pain procedure(e.g. epidural steroid injection, facet joint procedures, etc.); **AND**
        - Spine surgeon evaluation within last 12 months attesting that the patient is not a candidate for further surgical intervention; **OR**
    - Painful diabetic neuropathy (PDN) in lower extremity with **ALL** of the following:
        - Failure of at least a 3-month trial of at least 2 neuropathic medications (e.g., gabapentin, pregabalin, duloxetine, amitriptyline, nortriptyline, venlafaxine, desvenlafaxine, etc.); **AND**
        - Documentation (within last 6 months) from primary care physician or endocrinologist that medical management of diabetes and glucose control has been optimized; **AND**
        - Documentation of a hemoglobin A1c (HbA1c) level of 9 or less within the last 3 months; **OR**
- A **permanent SCS implantation** is appropriate if the patient has had a successful SCS trial, as indicated by **ALL** of the following[8]:
    - A temporary SCS trial of at least 3 days; **AND**
    - Demonstration of at least 50% reduction in pain during the temporary SCS trial; **AND**

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- Documented improvement in **ANY** of the following during the temporary SCS trial:
    - Ability to perform daily activities; **OR**
    - Quality of life; **OR**
    - Functional disability scale; **OR**
    - Mobility; **OR**
    - Use of pain medications; **OR**

- **A SCS or DRG revision or replacement** is considered appropriate if **ANY** of the following are **TRUE**[9-13]:
    - SCS/DRG battery malfunction or depletion; **OR**
    - Lead displacement or fracture; **OR**
    - Infection surrounding SCS device; **OR**
    - Hardware-related pain; **OR**
    - An MRI-compatible device is needed due to **ALL** of the following:
        - The patient currently has a non-MRI compatible device; **AND**
        - An MRI is required for concerns of disorders that cannot be properly evaluated by non-MRI imaging modalities; **AND**
        - A physician must attest to the medical necessity of an MRI.

Non-Indications

- A **spinal cord stimulator (SCS)** is not considered appropriate if **ANY** of the following is **TRUE**[8]:
    - Dorsal Root Ganglion (DRG) stimulation for all conditions except complex regional pain syndrome (CRPS) types I and II in lower extremity[14,15,16]; **OR**
    - SCS for all conditions except the indications covered in this policy: (Failed back surgery syndrome/ post-laminectomy syndrome, Complex Regional Pain Syndrome, Painful Diabetic neuropathy)
    - More than 2 SCS trials per anatomic spinal region per patient per lifetime is not considered reasonable and necessary[14]; **OR**
    - A repeat trial after initial trial failure, unless extenuating circumstances were present that contributed to trial failure[14]; **OR**
    - DRG or SCS trial in a patient with an existing SCS or DRG
    - Replacement or upgrade when **ANY** of the following is **TRUE**:
        - No documented medical necessity for upgrade of functional, non-MRI compatible SCS device; **OR**
        - The SCS is functioning, and newer technology is requested (including but not limited to BurstDR, high-frequency SCS, closed-loop SCS, etc.); **OR**

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- Lead and electrode replacement as both 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**.**

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
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 spinal neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array
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

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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

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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 the 6-month follow-up, patients with inadequate pain relief were given the option to begin the other treatment. The 142 patients treated with the 10 kHz SCS system were followed for 24 months. Results showed that at 24 months, the 10 kHz SCS reduced pain by an average of 79.9% compared to baseline, with 90.1% of patients experiencing at least 50% pain relief. Participants also experienced significant improvements in quality of life and sleep, with 65.7% demonstrating clinically meaningful neurological improvement. The study supports the use of 10 kHz SCS for lasting pain relief and notable improvements in quality of life, sleep, and neurological function over 24 months.[17]

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 2 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 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.[18]

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 8-to-10-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 8 years. The study notes that pain intensity during the day and night significantly decreased with SCS compared to baseline. More than 50% of patients experienced a pain reduction of more than 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 8 years.[19]

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In their systematic review and meta-analysis of implanted neuromodulation interventions, which included 908 randomized participants across 35 published or ongoing studies, O'Connell et al. (2022) found that patients treated with SCS experienced less pain and a higher quality of life 1-6 months after treatment, compared to patients who received only medical management or physical therapy. However, according to the authors, there is little evidence to suggest that SCS can reduce disability, medication use, or pain in the medium to long-term. Nor is it clear that SCS is cost-effective. The authors also note that possible complications of SCS implantation include lead displacement or fracture, wound infection, and the need for surgical revision or replacement.[20]

In a randomized clinical trial, Hara et al. (2022) investigated the efficacy of SCS. The placebo-controlled trial included 50 patients who underwent randomized 3-month periods of spinal cord burst stimulation and placebo stimulation. The study team did not find a significant difference in self-reported disability among trial participants with chronic post-lumbar spine surgery back pain.[21]

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