Spinal Cord Stimulators

Humana®
And Subsidiaries

Original Effective Date: 01/01/2024
Effective Date: 02/02/2026
Review Date: 01/13/2026
Policy Number: HUM-1215-007
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies
Description
Coverage Limitations
Coding Information
Change Summary
Related CMS Documents
Coverage Determination
Summary of Evidence
References

Disclaimer
The Medical Coverage Policies are reviewed by all Utilization Management Committees within Humana. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana and subsidiaries.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

Humana and subsidiaries apply a Medicare Administrative Contractor's (MAC's) LCD to all requests (both Part A and Part B services) within the MAC's applicable geographic jurisdiction.

Type	Title	Document ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
Internet-Only Manuals (IOMs)	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15	§80.2 Psychological Tests and Neuro-psychological Tests §120 Prosthetic Devices		
NCD	Electrical Nerve Stimulators	160.7		
LCD LCA	Spinal Cord Stimulators for Chronic Pain	L35136 A57791	JE - Noridian Healthcare Solutions, LLC JF - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Spinal Cord Stimulators for Chronic Pain	L37632 A56876	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV

Description

A spinal cord stimulator (SCS), also known as a dorsal column stimulator (DCS), is an implantable medical device used to treat chronic pain. The most common indications for a SCS include the management of failed back surgery syndrome (FBSS) and the treatment of complex regional pain syndrome (CRPS) (also known as reflex sympathetic dystrophy [RSD]), though it has also been proposed for other uses.

Spinal cord stimulation requires a surgical procedure, conducted in two phases, to place an electrode into the epidural space of the spinal column. The electrode is connected to a surgically implanted pulse generator (which contains the battery). An electrical impulse generated by the device travels to the electrode(s) where it creates a paresthesia (tingling sensation) which is thought to alter the perception of pain by the individual.

Temporary Percutaneous Electrode Placement
In the first phase of the spinal cord stimulation process, a local anesthetic is injected near the insertion site and an electrode is placed with the assistance of fluoroscopy to guide it to the desired level in the spinal column. Over the next few days, extensive testing with the temporary electrode is performed as an outpatient to measure the effectiveness and determine adequate positioning. If at least a 50% reduction in pain is reported, the individual returns for placement of permanent electrodes and a generator device.

Permanent Electrode Placement and Implantation of a Pulse Generator
In the second phase of the process, the individual is kept awake, though sedated, during the surgical procedure to help guide electrode placement and ensure that the SCS provides adequate parasthetic sensation over the intended affected area. Permanent electrodes are placed; a connector wire is tunneled under the skin and connected to an implantable pulse generator (IPG) which is inserted into a surgically prepared pocket in the abdomen or the upper posterior hip area.

Examples of SCS include, but may not be limited to, **Precision Novi SCS System**, **Precision Plus SCS System** and **Precision Spectra System**. The **Precision Montage MRI SCS**, **PrimeAdvanced SureScan**, **Prospera**, **RestoreAdvanced SureScan**, **RestoreSensor SureScan** and **RestoreUltra SureScan** are examples of SCS that have been approved by the US Food & Drug Administration (FDA) for use in a magnetic resonance imaging (MRI) scanner.

The **Evoke Spinal Cord Stimulation (SCS) System** is designed to operate in either of two modes: an evoked compound action potential (ECAP) controlled closed-loop stimulation mode, or an open-loop (fixed output) stimulation mode. The open-loop stimulation mode is said to be equivalent to that of traditional SCS and the closed-loop purportedly can provide real-time measurement as well as automatic adjustment of the strength of the stimulation based on the reading, recording and response to the ECAP.

The **Freedom Spinal Cord Stimulator System** is the first FDA-approved device to have the impulse generator/battery enclosed within the lead body/electrodes. The stimulator/electrodes are inserted percutaneously via a needle into the lumbar or thoracic epidural space. It is also MRI compatible.

The **Inceptiv SCS** received FDA approval as a closed-loop SCS. It is a rechargeable device whose closed-loop feature purports to sense biological signals along the spinal cord and automatically adjusts stimulation in real time, which theoretically maintains the prescribed stimulation regardless of activity or any other reasons for variances. It is also currently the only closed-loop SCS system that offers full body MRI access.

The **Intellis Spinal Cord Stimulator** platform system, in addition to being MRI compatible, is also FDA-approved to be controlled by an application (app) interface with an Android tablet. This, in theory, eliminates the need for device replacement when technology updates are developed, and also allows the physician or other healthcare professionals to monitor the usage of the SCS, as the app also records/tracks its activity. A similar device, the **Intellis with AdaptiveStim** stimulator has the added ability to automatically adjust the therapy waveform as the individual moves. The **Vanta with AdaptiveStim Implantable Neurostimulator**, in addition to the AdaptiveStim capability, is recharge-free and has a feature called differential target multiplexed (DTM) stimulation, a proprietary waveform that allows further individualization of the treatment.

The **Nalu Neurostimulation System** has been approved by the FDA for use as either a spinal cord stimulator or as a peripheral nerve stimulator. This system is described as a partially implanted, battery-free neurostimulation device. The pulse generator and leads are implanted, but the energy source is an externally worn radiofrequency generator battery (referred to as a therapy disc); it is controlled through a smartphone-based remote-control app.

The **Proclaim XR SCS System with BurstDR stimulation**, in addition to being MRI compatible, emulates the natural firing patterns in the brain, thereby modulating both the sensory and emotional pathways. This type of stimulation is theorized to give an individual relief from painful sensations and their conscious attention to pain, and reduce or eliminate the paresthesia that is felt with traditional spinal cord stimulation. This SCS is controlled by an app on Apple mobile devices which, in theory, eliminates the need for regular recharging or replacement when technology updates are developed. It has a battery life of up to 10 years at low dose settings. An additional variation of the Proclaim system is the **Proclaim Plus**; it utilizes FlexBurst360 therapy (their next generation of BurstDR therapy) which allows treatment of multisite pain. The **Prodigy MRI IPG with BurstDR stimulation** is a similar device to the Proclaim XR, using the same type of stimulation patterns, but does not have the capability to be controlled with any digital devices.

The **Senza HF-10 SCS** (rebranded as **HFX**) is the only device to receive FDA approval to treat chronic pain without creating/causing paresthesia, with a subsequent label expansion approval indicating MRI compatibility. The **Senza Omnia**, allows delivery of the HF-10 high-frequency wavelength as well as the option for delivery of other conventional stimulation frequencies. As with the other Senza device, it is also MRI compatible.

The **Spectra WaveWriter Spinal Cord Stimulator System** delivers paresthesia-based and subperception (no paresthesia) therapy simultaneously; this may also be described as dual-wave stimulation. This may allow customization of the therapy dependent on the individual and theoretically may be used in one of two ways: both therapy types can be combined to treat a specific area or used separately for managing multiple pain areas. The **WaveWriter Alpha** is MRI compatible and has the option for either a rechargeable or nonrechargeable battery.

The **Wavegate Ellipse with StimuLux technology** has been granted an FDA Breakthrough Device Designation; it is described as a system for closed-loop adaptive modulation of spinal cord stimulation (which may also be described as active loop). According to the manufacturer, it integrates optoelectronic components and optical fiber to measure the distance between the spinal cord and the epidural electrode array. This purportedly allows real-time stimulus modulation to ensure consistent and effective adaptive stimulation. Currently this device is only available in clinical trials.

Dorsal root ganglion stimulation differs slightly from traditional spinal cord stimulation and is proposed as a treatment of moderate to severe chronic intractable pain of the lower extremities in an adult with chronic CRPS. The **Proclaim DRG Neurostimulation System** (formerly the Axium Neurostimulator System) is an example of an FDA-approved dorsal root ganglion stimulator; it is also MRI compatible and uses wireless technology control via an Apple mobile digital device.

Coverage Determination

Humana and subsidiaries follow the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Humana and subsidiaries apply any applicable National Coverage Determination (NCD) and any applicable Local Coverage Determinations (LCDs) to the services and jurisdiction at issue. See the Related CMS Documents Section above for any such NCDs or LCDs.

In order to determine medical necessity consistently, Humana and subsidiaries may consider the criteria contained in the following:

Dorsal Root Ganglion Stimulation/Stimulators
The following criteria apply to ALL jurisdictions.

Dorsal root ganglion stimulation/stimulator will be considered medically reasonable and necessary for management of moderate to severe chronic intractable pain of the lower extremities in an adult with complex regional pain syndrome (CRPS) types I and II)[63], in lieu of a spinal cord stimulator, when the criteria for CRPS **AND** the criteria for a temporary trial, permanent implantation, replacement or revision/removal, as set forth below are met.[5,21]

Spinal Cord Stimulators
While NCD 160.7 Electrical Nerve Stimulators includes **spinal cord (dorsal column) neurostimulation** as nationally covered treatment, it does not provide criteria specific to when the use of **spinal cord stimulation** is considered medically reasonable and necessary (ie, does not fully define what is meant by chronic intractable pain [what conditions/diagnoses] or what constitutes a successful temporary trial). While the LCDs Spinal Cord Stimulators for Chronic Pain (**L35136, L37632** [**JE/JF, JJ/JM**]) indicate that spinal cord stimulators are best suited for neuropathic pain, they do not provide what evidence-based conditions/diagnoses are considered medically reasonable and necessary.

Therefore, **for ALL jurisdictions**, Humana and subsidiaries may consider the following to interpret or supplement such criteria in order to determine medical necessity consistently:

Spinal cord stimulator placement for a trial or permanent implantation will be considered medically reasonable and necessary when the following indications are met:

- Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)[6,18]:
    - Other treatment modalities have been tried and failed to provide satisfactory pain control, to include the following[18]:

- Interventional spinal procedure (eg, regional sympathetic nerve blocks, stellate ganglion blocks) if medically appropriate and not contraindicated, was tried and failed[18]
- Pharmacologic management[18] if medically appropriate and not contraindicated
- Physical therapy (PT),[18] including:
  - ❖ Treated with and failed aggressive PT with desensitization[18]; **OR**

- Diabetic neuropathy[1]:
  - Glycemic control prior to spinal cord stimulation trial[50]; **AND**
  - Other treatment modalities have been tried and failed to provide satisfactory pain control, to include the following[50]:
    - Pharmacological management[50] if medically appropriate and not contraindicated; **OR**

- Failed back surgery syndrome (FBSS)[48]:
  - When accompanied with primary radicular pain[48]; **AND**
  - Surgery has been tried and failed **AND** the individual with failed back surgery syndrome is not a candidate for further surgical interventions[48]; **AND**
  - Other treatment modalities have been tried and failed to provide satisfactory pain control, to include the following[48]:
    - Interventional spinal procedure (eg, epidural steroid injection, facet block, medial branch block, facet joint denervation) if medically appropriate and not contraindicated, was tried and failed[17]
    - Pharmacological management[48] if medically appropriate and not contraindicated
    - PT[48]; **OR**

- Inoperable chronic limb ischemia[6,16]:
  - Other treatment modalities have been tried and failed to provide satisfactory pain control, to include the following[14,17]:
    - Pharmacological management[17] if medically appropriate and not contraindicated; **OR**

- Low back pain, in the absence of failed back surgery syndrome[6,48]:

- When accompanied by predominantly radicular pain in the extremities[17]; **AND**
- Individual is not a surgical candidate **or** does not wish to have the surgical procedure[17]; **AND**
- Other treatment modalities have been tried and failed to provide satisfactory pain control, to include the following[48]:
  - Interventional spinal procedure (eg, epidural steroid injections, facet blocks, medial branch blocks, facet joint denervation) if medically appropriate and not contraindicated, was tried and failed[17];
  - Pharmacological management[48] if medically appropriate and not contraindicated;
  - PT[48]

Temporary Trial

A **temporary trial** of **spinal cord stimulation** will be considered medically reasonable and necessary for any of the conditions listed above (CRPS/RSD, FBSS with primarily radicular pain, inoperable chronic limb ischemia, low back pain [in the absence of FBSS] or painful diabetic neuropathy) when **ALL** of the following criteria are met:

- Absence of contraindications (active systemic infection[46,48]); **AND**
- Implantation of the stimulator is used only as a late (if not last) resort for individuals with chronic intractable pain[13] related to the conditions listed above; **AND**
- Pain has been present for at least 6 months[48]; **AND**
- Pain-focused psychological evaluation[46,48] by a licensed mental health professional***** has been obtained and indicates that the individual is a favorable candidate for spinal cord stimulation:
  - Submitted documentation must indicate no untreated comorbid psychological issues/conditions, individual has the cognitive abilities to operate the device[46,48] and that the individual is a good candidate for SCS; **AND**
- Procedure is performed by a physician[8-9]; **AND**
- The individual has undergone screening, physical evaluation and diagnosis by a multidisciplinary team prior to implantation[8-9,13]

Permanent Implantation

Permanent implantation of a **SCS** will be considered medically reasonable and necessary when a temporary trial has been successful. Successful is defined as:

- A temporary trial of at least 3 days duration has been completed,[57] **AND ALL** of the criteria listed above have been met; **AND**

- Demonstration of at least 50% reduction in pain, or 50% reduction in analgesic medication use, **AND** improved function with the temporary implanted electrode prior to the permanent implantation[6,8-9,48]

Replacement

Replacement of a **spinal cord stimulator** will be considered medically reasonable and necessary for any of the following[10]:

- A change in the physiological condition of the individual; **OR**

- An irreparable change in the condition of the device, or in a part of the device; **OR**

- The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of the replacement device, or as the case may be, of the part being replaced

Lead and electrode replacement are not generally required at the time of generator replacement due to end of battery life.

Revision or Removal

Revision or removal of a **spinal cord stimulator** will be considered medically reasonable and necessary for the following indications:

- Inadequate pain relief[57]; **OR**
- Infection[57]; **OR**
- Intolerance of paresthesia[57]; **OR**
- Lead fracture[57]; **OR**
- Lead migration[57]; **OR**
- Loss of effectiveness/tolerance[57]; **OR**
- Painful generator site[41]; **OR**
- Seroma[57]

*****Eligible licensed mental health professional may be a physician (Medical Doctors [MDs], Doctors of Osteopathy [Dos], particularly psychiatrists), Clinical Psychologists (CPs), Clinical Social Workers (CSWs), Clinical Nurse Specialists (CNSs), Nurse Practitioners (NPs [specifically, psychiatric NPs]), Physician Assistants (PAs), Independently Practicing Psychologists (IPPs) (supervision of diagnostic psychological and neuropsychological tests).[11]

The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to, lead migration, lead fracture, postoperative infection, dural puncture, development of a seroma, spinal cord injury or spinal epidural hematoma[57]). Services that do not meet the criteria above are not medically reasonable and necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following applies to ALL jurisdictions.

Spinal cord stimulation will **not** be considered medically reasonable and necessary for the following:

- Chronic stable angina pectoris[1]; **OR**
- Chronic visceral abdominal pain[46]; **OR**
- Replacement/upgrade of a *functioning* SCS that is not MRI compatible to one that is MRI compatible; **OR**
- Replacement/upgrade of a *functioning* SCS to a BurstDR or high-frequency SCS; **OR**
- Replacement/upgrade of a SCS when requested for convenience or to upgrade to a newer technology when the current device remains functional; **OR**
- Utilization of a spinal cord stimulation system with an all-in-one lead and generator[36]

Lead and electrode replacement are **NOT** generally required at the time of a generator replacement due to end of battery life.

A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment for these indications. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Lifetime Limitation for SCS
Reimbursement will be limited to placement of a maximum of 2 leads or 16 contacts, and for 2 SCS trials per anatomic spinal region per individual per lifetime (with exceptions allowed for technical limitations for the initial trials or for use of different modalities of stimulation, including new technology). More than 2 SCS

trials per anatomic spinal region per individual per lifetime is not considered reasonable and necessary.[7,Error! Reference source not found.]

Summary of Evidence

Chronic stable angina pectoris
The joint guideline from the American Heart Association (AHA) and American College of Cardiology (ACC),[1] in collaboration with and endorsed by the American College of Clinical Pharmacy (ACCP), American Society for Preventive Cardiology (ASPC), National Lipid Association (NLA) and Preventive Cardiovascular Nurses Association (PCNA), as well as endorsed by the Society for Cardiovascular Angiography and Interventions notes that, although the past decade has seen numerous advancements in the diagnosis and treatment of individuals with chronic coronary disease and refractory angina, several gaps still exist. The organizations recommend that further research is needed to assess the utility of spinal cord stimulation for individuals with chronic coronary disease and refractory angina.

An independent evidence-based guideline organization[46] also notes that for refractory angina pectoris, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit versus harm, and additional research is recommended.

Chronic visceral abdominal pain
An independent evidence-based guideline organization[46] notes that for chronic visceral abdominal pain, the evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit versus harm, and that additional research is needed. Additionally, the authors note a lack of consensus among pain management physicians regarding patient selection and appropriate lead placement of spinal cord stimulation for this condition.

Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)
Ho et al[42] provide a systematic review and meta-analysis of randomized controlled trials for spinal cord stimulation in CRPS. Four RCTs were identified that include SCS as a treatment arm for CRPS. The conclusion was that SCS is superior to conventional therapies or placebo SCS.

Levin and Sagher[15] report on a 5-year follow-up of a randomized controlled trial comparing SCS combined with physical therapy versus physical therapy alone. The authors found significantly better relief of symptoms in patients receiving SCS than patients receiving conservative management during the first 3 years following implantation.

An evidence-based clinical resource[52] notes that spinal cord stimulation may be helpful if traditional therapeutic modalities fail, particularly in an individual with disease limited to one extremity. Additionally, it is noted that SCS plus physical therapy reduced pain and improved health-related quality of life more than PT alone for up to two years in a study of 36 patients and 18 controls but did not improve functional outcome measures. No difference in pain was present during the period from three to five years following implantation. And, in another small trial of 31 patients with CRPS, tonic SCS improved sensory thresholds and reduced pain, allodynia, and hyperalgesia at three-month follow-up.

Deer et al[19] provides a systematic literature review of dorsal root ganglion (DRG) stimulation in the treatment of CRPS. Prospective trials (randomized controlled trials and observational studies) that were not part of a larger or previously reported group were included in the review. The authors found level II evidence (moderate) based upon one high-quality pivotal randomized controlled trial, one high-quality perspective trial and four moderate-quality trials/observational studies, allowing the conclusion to be drawn that moderate-level evidence supports DRG stimulation for treating this population. Dorsal root ganglion stimulation is limited to treatment of lower extremity CRPS, as indicated by the FDA approval.[63]

Diabetic neuropathy

Peterson et al[50] conducted a 24 month randomized controlled trial (RCT) evaluating the long-term efficacy of high-frequency 10 kHz SCS for the treatment of painful diabetic neuropathy. That multicenter trial compared conventional medical management (CMM) alone to 10kHz SCS plus CMM. After the first 6 months, participants with insufficient pain relief could cross over to the other treatment; as a result, 142 individuals were treated with SCS. At 24 months, the SCS reduced pain by a mean of 79.9% compared to baseline, with 90.1% of participants reporting at least 50% pain relief, as well as improved health-related quality of life (HRQoL) and sleep, and 65.7% demonstrated clinically meaningful neurological improvement.

In the 2022 update to the American Association of Clinical Endocrinology[1] clinical practice guideline, spinal cord stimulation is now addressed as a treatment option that should be considered for individuals with refractory painful diabetic peripheral neuropathy (DPN). Specifically, the authors note that high frequency SCS is a nonpharmacological approach that may be effective in persons with painful DPN that failed at least one medication.

Failed back surgery syndrome (FBSS)

According to an evidence-based clinical resource review,[57] there is moderate-quality evidence supporting the use of spinal cord stimulation in an individual with persistent radicular pain due to FBSS. In a separate report, the same organization[58] noted one randomized trial found SCS superior to reoperation for individuals with persistent low back pain after spinal surgery, achieving greater than 50 percent pain relief. In another randomized trial, 100 participants with persistent radicular pain following surgery for herniated disc were found to have SCS associated with greater likelihood of experiencing greater than 50 percent pain relief at 6 months versus those with conventional medical management.

Levin and Sagher[16] provide a review of the PROCESS trial (Prospective, Randomized, Controlled, Multicenter Study of Patients with Failed Back Surgery Syndrome), which was a large, multicenter, randomized controlled trial of SCS. The data from that trial followed pain relief and cost-effectiveness of SCS compared with conventional medical management. Pain relief was significantly better in individuals treated with spinal cord stimulators compared with those receiving conventional management; the same treatment group also reported significant improvement in health care-related quality of life. Another study reviewed by the same authors reports on a randomized controlled trial (RCT) which examines the role of SCS in the management of FBSS, comparing it to repeat lumbar spine surgery; although it was a small trial (42 participants), SCS proved more effective than redo spine surgery. Participants in that study who failed to benefit from that second spine surgery subsequently had treatment with SCS and achieved good results as well.

Inoperable chronic limb ischemia
Levin and Sagher[16] explain that through a combination of sympathetic outflow modulation and antidromic activation of sensory fibers, SCS acts to dilate peripheral vasculature, thereby potentially altering vascular flow and improving tissue perfusion. The use of SCS in the treatment of peripheral vascular disease was first proposed in the 1970s. Subsequently, stimulator placement in the low thoracic or lumbar region of the spine has been shown to be effective in the treatment of pain caused by lower extremity peripheral artery occlusive disease.

Low back pain (in the absence of failed back surgery syndrome)
Huygen et al[44] includes 13 randomized clinical trials and 1561 patients in a systematic review and meta-analysis, finding that both conventional and novel SCS are associated with superior efficacy versus conventional medical management after 6 months of follow-up across 5 of 6 outcomes. The primary outcomes were pain-related end points, including pain intensity (measured by visual analog scale) and proportion of patients achieving at least 50% pain relief (responder rate) in the back or leg. Quality of life (measured by EQ-5D index score) and functional disability (measured by the Oswestry Disability Index score) were also considered. Specifically, patients treated with SCS therapies are more likely to achieve at least 50% pain reduction in either back or leg when measured at 6 months of follow-up.

Spinal cord stimulation systems with an all-in-one lead and generator
In the report that reviewed the Freedom SCS for treatment of back pain, an independent technology assessment organization[36] concludes that there is insufficient published evidence specifically related to the device to assess its safety and/or impact on health outcomes. The author notes there have not been any randomized controlled trials, or any other type of studies, performed/published evaluating this device compared with sham, placebo or active treatment.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
63650	Percutaneous implantation of neurostimulator electrode array, epidural	
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural	
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed	

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, direct or inductive coupling	
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver	
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	
CPT® Category III Code(s)	**Description**	**Comments**

0784T	Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed	
0785T	Revision or removal of neurostimulator electrode array, spinal, with integrated neurostimulator	
0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters	
0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters	
HCPCS Code(s)	**Description**	**Comments**
C1767	Generator, neurostimulator (implantable), nonrechargeable	
C1778	Lead, neurostimulator (implantable)	
C1787	Patient programmer, neurostimulator	
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	
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	
C1897	Lead, neurostimulator test kit (implantable)	
L8679	Implantable neurostimulator, pulse generator, any type	
L8680	Implantable neurostimulator electrode, each	

L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	
L8682	Implantable neurostimulator radiofrequency receiver	
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension	
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only	

References

1. American Association of Clinical Endocrinology (AACE). Clinical Practice Guidelines. American Association of Clinical Endocrinology clinical practice guideline: developing a diabetes mellitus comprehensive care plan - 2022 update. https://pro.aace.com. Published August 2, 2022.

2. American College of Cardiology (ACC). 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease. https://acc.org. Published 2023.

3. American College of Cardiology (ACC). 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVS/SIR/ VESS guideline for the management of lower extremity peripheral artery disease. https://acc.org. Published 2024.

4. American Society of Interventional Pain Physicians (ASIPP). An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. https://asipp.org. Published 2013.

5. American Society of Pain and Neuroscience (ASPN). Best practices for dorsal root ganglion stimulation for chronic pain: guidelines from the American Society of Pain and Neuroscience. https://aspnpain.com. Published March 2023.

6. American Society of Regional Anesthesia and Pain Medicine (ASRA). Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. https://asra.com. Published March 31, 2023.

7. Bolash R, Creamer M, Rauck R, et al. Multi-waveform spinal cord stimulation with high frequency electromagnetic coupled (HF-EMC) powered implanted electrode array and receiver for the treatment of chronic back and leg pain (SURF study). *Pain Phys.* 2022;25:67-76.

8. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L35136). https://cms.gov. Published October 1, 2015. Updated October 16, 2025.

9. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L37632). https://cms.gov. Published January 29, 2018. Updated May 13, 2021.

10. Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual. Covered medical and other health services - prosthetic devices. https://cms.gov. Published October 1, 2003. Updated June 13, 2024.

11. Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual. Covered medical and other health services - psychological tests and neuropsychological tests. https://cms.gov. Published October 1, 2003. Updated June 13, 2024.

12. Centers for Medicare & Medicaid Services (CMS). Medicare Learning Network Booklet. Medicare & mental health coverage. https://cms.gov. Published July 2024.

13. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Electrical nerve stimulators (160.7). https://cms.gov. Published August 7, 1995.

14. ClinicalKey. Durbhakula S, Malik K. Spinal cord stimulation. In: Benzon H. *Essentials of Pain Medicine.* 4th ed. Elsevier; 2018:663-676.e2. https://clinicalkey.com.

15. ClinicalKey. Lamer T, Moeschler S, Gazelka H, Hooten W, Bendel M, Murad H. Spinal stimulation for the treatment of intractable spine and limb pain: a systematic review of RCTs and meta-analysis. *Mayo Clin Proc.* 2019;94(8):1475-1487. https://clinicalkey.com.

16. ClinicalKey. Levin E, Sagher O. Spinal cord stimulation. In: Winn R. *Youmans and Winn Neurological Surgery.* 8th ed. Elsevier; 2023:1548-1555.e3. https://clinicalkey.com.

17. ClinicalKey. Refaey K, Vlasak A, Ramos-Fresnedo A, Ball P, Reimer R, Nottmeier E. Spinal cord stimulation and intraspinal infusions for pain. In: Quinones-Hinojosa A. *Schmidek and Sweet: Operative Neurosurgical Techniques.* 7th ed. Elsevier; 2022:1378-1389.e2. https://clinicalkey.com.

18. ClinicalKey. Williams K, Guarino A, Raja S. Complex regional pain syndrome. In: Benzon H. *Essentials of Pain Medicine.* 4th ed. Elsevier; 2018:223-232.e2. https://clinicalkey.com.

19. Deer T, Hunter C, Mehta P, et al. A systematic literature review of dorsal root ganglion neurostimulation for the treatment of pain. *Pain Med.* 2020;21(8):1581-1589.

20. Deer T, Levy R, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *J Pain*. 2017;158(4):669-681.

21. Deer T, Pope J, Lamer T, et al. The Neuromodulation Appropriateness Consensus Committee on best practices for dorsal root ganglion stimulation. *Neuromodulation.* 2019;22(1):1-35.

22. Dhruva S, Murillo J, Ameli O, et al. Long-term outcomes in use of opioids, nonpharmacologic pain interventions, and total costs of spinal cord stimulators compared with conventional medical therapy for chronic pain. *JAMA Neurol.* 2022;E1-E13.

23. ECRI Institute. Clinical Evidence Assessment. AdaptiveStim spinal cord stimulation technology (Medtronic plc.) for treating chronic pain. https://home.ecri.org. Published September 29, 2021. Updated October 31, 2023.

24. ECRI Institute. Clinical Evidence Assessment. BurstDR spinal cord stimulation technology (Abbott Laboratories) for treating chronic pain. https://home.ecri.org. Published June 6, 2024.

25. ECRI Institute. Clinical Evidence Assessment. Evoke Spinal Cord Stimulator (Saluda Medical) for treating chronic pain. https://home.ecri.org. Published July 19, 2022. Updated October 31, 2023.

26. ECRI Institute. Clinical Evidence Assessment. Outpatient spinal cord stimulator implantation for treating chronic pain. https://home.ecri.org. Published July 20, 2022.

27. ECRI Institute. Clinical Evidence Assessment. Proclaim DRG Neurostimulation System (Abbott Laboratories) for treating complex regional pain syndrome. https://home.ecri.org. Published May 18, 2021.

28. ECRI Institute. Clinical Evidence Assessment. Proclaim Plus Spinal Cord Stimulation System (Abbott Laboratories) for treating chronic pain. https://home.ecri.org. Published February 1, 2023.

29. ECRI Institute. Clinical Evidence Assessment. Prospera Spinal Cord Stimulation System (Biotronik NRO, Inc.) for treating chronic pain. https://home.ecri.org. Published August 10, 2023.

30. ECRI Institute. Clinical Evidence Assessment. Senza Spinal Cord Stimulation System (Nevro Corp.) for treating chronic pain. https://home.ecri.org. Published November 6, 2014. Updated May 26, 2022.

31. ECRI Institute. Clinical Evidence Assessment. Spinal cord stimulation for treating peripheral neuropathy. https://home.ecri.org. Published December 31, 2012. Updated March 5, 2024.

32. ECRI Institute. Product Brief. Algovita Spinal Cord Stimulation System (Nuvectra Corp.) for treating chronic pain. https://home.ecri.org. Published July 31, 2018.

33. ECRI Institute. Product Brief. Protégé SCS (St. Jude Medical) for treating chronic pain. https://home.ecri.org. Published July 21, 2015.

34. ECRI Institute. Product Brief. Protégé Upgradeable IPG Neurostimulator (St. Jude Medical) for treating chronic pain. https://home.ecri.org. Published August 1, 2014.

35. ECRI Institute. Product Brief. RestoreSensor, RestoreUltra, and RestoreAdvanced Neurostimulators (Medtronic, Inc.) for managing chronic pain. https://home.ecri.org. Published July 21, 2015.

36. Hayes, Inc. Evidence Analysis Research Brief. Freedom Spinal Cord Stimulator System (Curonix LLC) for treatment of chronic back pain. https://evidence.hayesinc.com. Published May 28, 2025.

37. Hayes, Inc. Evidence Analysis Research Brief. Proclaim XR Spinal Cord Stimulation System (Abbott) for management of diabetic peripheral neuropathy. https://evidence.hayesinc.com. Published September 8, 2023.

38. Hayes, Inc. Evolving Evidence Review. Evoke Spinal Cord Stimulation System (Saluda Medical Pty Ltd.) for chronic intractable pain. https://evidence.hayesinc.com. Published November 17, 2022. Updated December 9, 2024.

39. Hayes, Inc. Health Technology Assessment. Dorsal root ganglion stimulation for the treatment of complex regional pain syndrome. https://evidence.hayesinc.com. Published December 28, 2021. Updated December 9, 2024.

40. Hayes, Inc. Medical Technology Directory. Electrical spinal cord stimulation for the treatment of intractable angina pectoris. https://evidence.hayesinc.com. Published October 23, 2014. Updated October 9, 2018.

41. Hayes, Inc. Medical Technology Directory. Spinal cord stimulation for relief of neuropathic pain. https://evidence.hayesinc.com. Published December 21, 2018. Updated March 27, 2023.

42. Ho E, Yazdanpanah N, Ho J, Drukman B, Chang A, Agarwal S. Parameters of spinal cord stimulation in complex regional pain syndrome: systematic review and meta-analysis of randomized controlled trials. *Pain Phys.* 2022;25:521-530.

43. Huygen F, Kallewaard J, Nijhuis H, et al. Effectiveness and safety of dorsal root ganglion stimulation for the treatment of chronic pain: a pooled analysis. *Neuromodulation.* 2020;23(2):213-221.

44. Huygen F, Soulanis K, Rtveladze K, Kamra S, Schlueter M. Spinal cord stimulation vs medical management for chronic back and leg pain. *JAMA Network Open.* 2024;7(11):e2444608.

45. Kapural L, Yu C, Doust M, 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;123(4):851-860.

46. MCG Health. Implanted electrical stimulator, spinal cord. https://humana.access.mcg.com/index.

47. Mekhail N, Levy R, Deer T, et al. Durability of clinical and quality-of-life outcomes of closed-loop spinal cord stimulation for chronic back and leg pain. A secondary analysis of the Evoke randomized clinical trial. *JAMA Neurol.* 2022;79(3):251-260.

48. North American Spine Society (NASS). Coverage Policy Recommendations. Spinal cord stimulation. https://spine.org. Published October 2017.

49. North American Spine Society (NASS). Evidence-based clinical guidelines for multidisciplinary spine care. Diagnosis and treatment of low back pain. https://spine.org. Published 2020.

50. Peterson E, Stauss T, Scowcroft J, 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;203:110865.

51. Srinivasan N, Zhou B, Park E. Dorsal root ganglion stimulation for the management of phantom limb pain: a scoping review. *Pain Phys.* 2022;25:E1173-E1181.

52. UpToDate, Inc. Complex regional pain syndrome in adults: treatment, prognosis, and prevention. https://uptodate.com. Updated April 2025.

53. UpToDate, Inc. Interventional therapies for chronic pain. https://uptodate.com. Updated April 2025.

54. UpToDate, Inc. Investigational therapies for treating symptoms of lower extremity peripheral artery disease. https://uptodate.com. Updated April 2025.

55. UpToDate, Inc. Management of diabetic neuropathy. https://uptodate.com. Updated April 2025.

56. UpToDate, Inc. New therapies for angina pectoris. https://uptodate.com. Updated April 2025.

57. UpToDate, Inc. Spinal cord stimulation: placement and management. https://uptodate.com. Updated April 2025.

58. UpToDate, Inc. Subacute and chronic low back pain: surgical treatment. https://uptodate.com. Updated April 2025.

59. US Department of Veterans Affairs (VA). VA/DoD Clinical Practice Guideline. Rehabilitation of individuals with lower limb amputation. https://va.gov. Published December 2024.

60. US Department of Veterans Affairs (VA). VA/DoD Clinical Practice Guideline. The diagnosis and treatment of low back pain. https://va.gov. Published February 2022.

61. US Food & Drug Administration (FDA). 510(k) summary: Freedom Spinal Cord Stimulator (SCS) System. https://fda.gov. Published October 10, 2014.

62. US Food & Drug Administration (FDA). 510(k) summary: Nalu Neurostimulation System. https://fda.gov. Published July 15, 2020.

63. US Food & Drug Administration (FDA). Premarket approval (PMA): Axium Neurostimulator System. https://fda.gov. Published February 11, 2016.

64. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Saluda Medical Evoke SCS System. https://fda.gov. Published February 28, 2022.

65. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Senza Spinal Cord Stimulation (SCS) System. https://fda.gov. Published May 8, 2015.

66. Wahezi S, Yener U, Naeimi T, et al. Spinal cord stimulation explantation and chronic pain: a systematic review and technology recommendations. *J Pain Res.* 2025;18:1327-1340.

Change Summary

01/01/2024 New Policy
06/11/2024 Update, Coverage Change
09/10/2024 Update, Coverage Change
11/05/2024 Annual Review, Coverage Change
12/10/2024 Update, Coverage Change
04/01/2025 Update, Coverage Change
09/02/2025 Annual Review, Coverage Change
02/02/2026 Update, No Coverage Change