Spinal Cord Stimulators

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medicare Advantage Medical/Pharmacy Coverage Policies
Related Documents
Description
Coverage Determination
Coverage Limitations
Coding Information
References
Change Summary

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

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

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
Internet-Only	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15			

Manuals (IOMs)	Section 120 - Prosthetic Devices	Medicare Benefit Policy Manual		
NCD	Electrical Nerve Stimulators	160.7		
LCD LCA	Spinal Cord Stimulators for Chronic Pain	L35136 A57791	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Spinal Cord Stimulators for Chronic Pain	L36204 A57792	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Spinal Cord Stimulators for Chronic Pain	L37632 A56876	JJ - Palmetto GBA	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 2 to 3 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.

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 is able to 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.

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. Their newest version is the **Vanta with AdaptiveStim Implantable Neurostimulator**. In addition to the AdaptiveStim capability, this stimulator is recharge-free, and also 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 Elite Recharge-Free 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 also reduce or eliminate the paresthesia that is felt with traditional spinal cord stimulation. This SCS is controlled by an app on Apple mobile digital devices which, in theory, eliminates the need for regular recharging or replacement when technology updates are developed. The **Proclaim XR** has the same capabilities as the Proclaim Elite, however 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 , 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** was the first, and remains the only, device to receive FDA approval to treat chronic pain without creating/causing paresthesia, with a subsequent label expansion approval indicating MRI

compatibility. Their newest version, 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 devices, 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. Two newer versions, the **WaveWriter Alpha** and the **WaveWriter Alpha-Prime** are both MRI compatible; the WaveWriter Alpha has a rechargeable battery, while the WaveWriter Alpha-Prime has a nonrechargeable battery.

The **Wavegate StimuLux** has been granted an FDA Breakthrough Device Designation; it is described as a system for closed-loop adaptive modulation of spinal cord stimulation. 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

iCare follows the CMS requirements that only allows 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.

Please refer to the above CMS guidance for **Spinal Cord Stimulators**

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Spinal Cord Stimulators

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. 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

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. Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual. Covered medical and other health services - prosthetic devices. https://www.cms.gov. Published October 1, 2003. Updated October 12, 2023. Accessed November 14, 2023.

2. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L36204). https://www.cms.gov. Published June 1, 2016. Updated December 1, 2019. Accessed November 14, 2023.

3. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L37632). https://www.cms.gov. Published January 29, 2018. Updated May 13, 2021. Accessed November 14, 2023.

4. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L35136). https://www.cms.gov. Published October 1, 2015. Updated December 1, 2019. Accessed November 14, 2023.

5. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Electrical nerve stimulators (160.7). https://www.cms.gov. Published August 7, 1995. Accessed November 14, 2023.

Change Summary

- 01/01/2024 New Policy.