Boston Scientific
Advancing science for life™

SPINAL CORD STIMULATION (SCS) REPLACEMENT MEDICAL NECESSITY DOCUMENTATION RECOMMENDATIONS

NOTE: Additional criteria may be required based on the medical policy used by the insurance

SUMMARY CAPTION	CONDITION

Replacement Rationale	Stimulator replacement may be considered medically necessary for any of the following criteria detailed in clinical notes.
	
	• Stimulator hardware complications including:
	  ○ Lead migration
	  ○ Infection
	  ○ Painful generator site
	• Stimulator response complications including
	  ○ Loss of effectiveness (e.g., increased, or recurrent pain and decreased function)
	  ○ Inability to charge or maintain a charge *
	• Planned procedure where stimulators may be contraindicated, include medical necessity for:
	  ○ MRI, when other tests are inconclusive (such as a CT Myelogram, EMG/NCS, plain x-rays with multiple views)
	  ○ Automatic implantable cardioverter defibrillator (AICD)
	
	If a telemetry report* is unavailable, include detailed explanation (e.g., the battery is unchargeable, specific reasons for inability to connect, or battery malfunction).

Type of device	Include note stating whether the device being replaced is: • Rechargeable or • Non-rechargeable.
Date of the original implant	Provide: • Clinical/office notes documenting the date of implant and/or • Procedure notes from the implant.

Provide the device's warranty statement, as requested by some payers	Some payers require providers to present the device's warranty statement. The BSC warranty statement is provided for your reference SCS Warranty: https://www.bostonscientific.com/content/dam/ewarranty/us-and-eu/neuromodulation/current-revision-neuro/Warranty_SCS_US_09_10_s.pdf Warranty Homepage: https://www.bostonscientific.com/eWarranty/home.html

*Many payer coverage policies for spinal cord stimulation require a telemetry report as part of the prior authorization process to help demonstrate medical necessity. In a spinal cord stimulation telemetry report, the following information is typically documented[1]:

- Device-related metrics (eg, stimulation usage, battery life)
- Measurable physiologic or disease-related metrics (eg, patient physical activity or pedometry)
- Patient-reported metrics (eg, sleep quality and pain intensity).

Telemetry reports become even more important when trying to demonstrate medical necessity of an IPG replacement. Often, the payer will want documentation validating the battery life of the existing IPG. In these situations, it may be helpful to:

- Create a PDF document that can be generated through the complaints tab in the XXXXX showing the IPG is at the end of life or not holding a charge.
- In the Letter of Medical Necessity mention for example, the inability to charge the battery for X time period and/or for the battery to hold the charge (Charge Burden), results in the patients lack of pain coverage.
- Include a programming report downloaded from the CP, if available, documenting the charging and usage cycle of the IPG.

https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=240

Indications for Use: The Boston Scientific Spinal Cord Stimulator Systems are indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, Complex Regional Pain Syndrome (CRPS) Types I and II, Diabetic Peripheral Neuropathy of the lower extremities, intractable low back pain and leg pain, radicular pain syndrome, radiculopathies resulting in pain secondary to failed back syndrome or herniated disc, epidural fibrosis, degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, multiple back surgeries. The Boston Scientific Spectra WaveWriter™, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems are also indicated as an aid in the management of chronic intractable unilateral or bilateral low back and leg pain without prior back surgery. Contraindications, warnings, precautions, side effects. The SCS Systems are contraindicated for patients who: are unable to operate the SCS System, have failed trial stimulation by failing to receive effective pain relief, are poor surgical candidates, or are pregnant. Refer to the Instructions for Use provided with the SCS System or Pain.com for potential adverse effects, warnings, and precautions prior to using this product.

Warning: Stimulation modes. Only paresthesia-based stimulation mode has been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Disclaimer: Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters. Boston Scientific does not promote the use of its products outside their FDA- approved label. Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements.
All trademarks are the property of their respective owners.
The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options This coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the
interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgement of the HCP.
Information included herein is current as of November 2024 but is subject to change without notice. Rates for services are effective January 1, 2025.

[1] Remote Management of Spinal Cord Stimulation Devices for Chronic Pain: Expert Recommendations on Best Practices for Proper Utilization and Future Considerations
Staats, Peter et al. Neuromodulation, Volume 26, Issue 7, 1295 - 1308