

Dear Provider:

Boston Scientific is committed to supporting providers when recommending Spinal Cord Stimulation as a treatment option to the indicated patients diagnosed with chronic pain of trunk and limb. This support includes resources when navigating insurance for patient access.

You may use the sample template which is included for your patients specific medical necessity submission for Spinal Cord Stimulation therapy.

Should you have additional questions, please contact your Regional Reimbursement and Sales Managers. Thank you,

BSC Health Economics and Market Access (HEMA) Team

**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.

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**Sample Template to Establish SCS Medical Necessity**

This template is designed to assist a provider in securing coverage for Spinal Cord Stimulation. This template is not intended to replace any professional judgement; it is merely to assist with the structure of the coverage request. There are several places in red within this template that encourage patient- specific information. Please review this letter once you have personalized it to the specific patient and eliminate all red fonts and template-related directions.

Date

Insurance Name

Attn: Pre-Authorization Department Street Address

City, State, Zip

Patient Name:

ID Number:

Group Number:

Date of Birth:

Procedure Codes: Specify Trial or Implant Code(s)

63650 Percutaneous implantation of neurostimulator array, epidural - x # of electrodes

63685 Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

Principle Diagnosis: (Insert Diagnosis here) To Whom It May Concern:

I am writing on behalf of the above-referenced patient, (Patient Name), to establish medical necessity and secure coverage for a spinal cord stimulator (Trial or Implant) to treat chronic intractable pain.

Spinal cord stimulation (SCS) is a proven, non-opioid, FDA-approved way to manage chronic pain. SCS works by disrupting the pain signals traveling between the spinal cord and the brain.

Unlike other pain management procedures, the benefit of SCS therapy to the patient can be assessed from a trial procedure, which is performed by a physician prior to the system implant. During the trial procedure, temporary leads are placed in the epidural space at the spinal levels corresponding to the pain pattern and are attached to an external power source to validate SCS therapy effectiveness. The trial procedure allows the patient to temporarily experience neurostimulation and the effect stimulation has on pain control. This allows the patient to make an informed choice about pursuing the therapy and allows the physician to interpret if neurostimulation is an appropriate intervention for the patient.

Spinal Cord Stimulation is a late or last resort treatment for chronic intractable pain where all minimally invasive options should be tried first. Below is a list of treatments that have been tried and failed for this patient.

|  |  |
| --- | --- |
| **Medical Necessity Requirements** | **Documentation confirmed in medical note** |
| Pharmacology Management – min. of 6 months | completed |
| Previous Medical Management – injections, etc. | completed |
| Conservative Therapies – physical therapy, etc. | completed |
| Phycological Evaluation | completed |
| Trial Documentation >50% improvement | Completed (if requesting trial delete this line) |
| Non-Surgical Candidate – Surgeon visit noted | Completed |

(Patient Name) has failed greater than 6 months of conservative pharmacology and conservative therapies and continues to have chronic pain. The recommendation of SCS therapy has distinct advantages for this patient and has been proven clinically effective, offering the prospect of enabling chronic pain patients to return to activities of daily living and potentially discontinue or reduce the use of opioids. My patient has undergone careful phycological evaluation by a licensed healthcare professional and has no known addictions and is a suitable candidate for therapy.

(Patient Name) Meets diagnostic criteria of DPN with evidence of painful DPN at least 12 months, Lower limb pain intensity of (insert VAS scale outcomes), Objective evidence for presence of neuropathy and severity (e.g., moderate-severe neuropathy), (EMG/NCS results), Confirmation of DPN diagnosis by at least one other specialist (e.g., neurologist), BMI (insert BMI score), HbA1c (insert HbA1c level), Daily morphine equivalents (insert dosage of morphine), Documented medical clearance as candidate for the procedure (Psychological Evaulation), Other causes of neuropathy have been ruled out.

It is my professional opinion that the implantation of a spinal cord stimulator would provide significant clinical and quality of life benefits for my patient. SCS treatment is medically necessary for my patient and appropriate for this stage of chronic pain disease.

Please contact me directly if you require additional information or if you would like to discuss the specifics of this case. I can be reached at PHONE # or by email at EMAIL ADDRESS.

Thank you in advance for your consideration of this request. Sincerely,

Physician Name Facility Name Full Address Phone

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