Check List for Documentation of Medical Necessity
Diabetic Peripheral Neuropathy
Spinal Cord Stimulation: Pre-Authorization Request

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Enabling timely access to care deemed medically necessary by the physician and patient, Boston Scientific has summarized payer requirements for coverage below. Checklists are illustrative only and may differ from payer to payer. Along with illustrative tools prepared by Boston Scientific, the following payer checklist of offered as a guide. Medical records must reflect accurate information based on the presentation of each patient, with requests for insurance coverage and claims submission supported through good documentation of the medical record.

Please refer to specific benefits and coverage requirements of each patients meeting unique payer requirements:

Step 1: Payer Diagnostic Criteria for DPN:

- Evidence of painful DPN of at least 12 months
- Lower limb pain intensity of ≥ 5 on the VAS scale
- Objective evidence for presence of neuropathy and severity: moderate-severe neuropathy on EMG/NCS (electromyography/nerve conduction studies)
- Confirmation of DPN diagnosis by at least one other specialist (e.g., neurologist)
- BMI ≤ 35
- HbA_{1c} ≤ 10%
- Daily morphine equivalents of 120 mg or less
- Documented medical clearance as candidate for the procedure
- Other causes of neuropathy have been ruled out

Step 2: Payer Clinical Criteria for SCS:

- Optimization of medical management (i.e., diabetes, inflammatory/infectious, vitamin/nutritional deficiencies, renal failure, possible Rx drug/iatrogenic, exposure to toxins)
- Failed trial (or documented intolerance) to multiple pharmacologic agents in at least 2 categories (i.e., antidepressants like duloxetine (Cymbalta), anticonvulsants like gabapentin/pregabalin, topicals like capsaicin, etc.)
- Severe pain and disability with documented pathology or an objective basis for the pain
- Dorsal column stimulation is being used as a late or last resort after documented failure of at least 6 consecutive months of physician-supervised multimodal conservative management
- There is no evidence of existing untreated drug addiction

- The patient has been evaluated by a pain management specialist prior to implantation
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient must be available.
- Documentation of an evaluation by a licensed mental health provider within 6 months of a stimulator trial request (e.g., a face-to-face assessment or with or without psychological questionnaires and/or psychological testing) that confirms no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a spinal cord stimulator or contraindicate its placement

For Permanent Implant Requests - Note SCS trial results including:

- >50% documentation of pain relief
- Improvements and functional gains in activities of daily living
- Any decreases in medications during the trial

Should you have any questions, please contact Boston Scientific's Patient Therapy Access Department at 866-287-0778.

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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