Boston Scientific
Advancing science for life™

Spinal Cord Stimulation (SCS) Medical Necessity Documentation Recommendations Confirming Late or Last Resort for SCS Trials and Implants – Aetna Commercial Plans

NOTE: Additional coverage criteria may be required based on the medical policy used by the insurance company, Medicare Replacement plans will follow NCD or LCD guidelines however when coverage criteria is not fully established using the NCD or LDC Aetna may review based on their internal coverage criteria.

INDICATION	INDICATION ELIGIBILITY	REQUIRED CLINICAL / CONSERVATIVE TREATMENT	IMPLANT REQUIREMENTS
Failed Back Surgery Syndrome (FBSS)	• Lumbar Spinal Pain of unknown origin either persisting despite surgical Intervention or appearing after surgical intervention for spinal pain originally in the same topographical location. And must have the following • Low Back Pain • Significant radicular pain	• Undergone Screening, Evaluation and diagnosis by a multidisciplinary team (Must Include Psychological and Physician Evaluations) • Psychological Clearance (Must be from a Psychiatrist, Psychologist, or Master of Social Work in Behavioral Health) • No untreated existing substance use disorder/s • Physician-directed Home Exercise Program, PT or OT ≥ 6 months • NSAIDs, antidepressant and anticonvulsant drugs ≥ 6 months • Oswestry Disability Index (ODI) Assessment with a score ≥ 21%	• Trial duration ≥ 5 days • Documented pain reduction ≥ 50%* • Demonstrated understanding of use of stimulator
Complex regional pain syndrome (CRPS)/RSD	• Continuing pain, which is disproportionate to any inciting event • Diagnosed using Budapest clinical criteria (2010 version) • Must have at least one symptom in three of the Following categories and display at least one sign on physical examination in two or more categories: • Sensory: Reports and evidence of hyperesthesia, hyperalgesia and/or allodynia • Vasomotor: Reports and evidence of temperature asymmetry and/or skin color changes and/or skin color asymmetry • Sudomotor/edema: Reports and evidence of edema • sweating changes and/or sweating asymmetry • Motor/trophic: Evidence of decreased range of motion, and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin); And • Chronic Intractable Pain of the upper and lower extremities • The use of Cervical SCS is allowed when members meet all listed criteria. There is no other medical or psychological diagnosis that better explains the signs and symptoms	• Undergone Screening, Evaluation and diagnosis by a multidisciplinary team (Must Include Psychological and Physician Evaluations) • Psychological Clearance (Must be from a Psychiatrist, Psychologist, or Master of Social Work in Behavioral Health) • No untreated existing substance use disorder/s • Physician-directed Home Exercise Program, PT or OT ≥ 6 months • NSAIDs, antidepressant and anticonvulsant drugs ≥ 6 months • Oswestry Disability Index (ODI) Assessment with a score ≥ 21%	• Trial duration ≥ 5 days • Documented pain reduction ≥ 50%* • Demonstrated understanding of use of stimulator
Chronic Neuropathic Pain/Peripheral Neuropathy (including DPN)	• Last resort treatment of severe chronic neuropathic pain of certain origins that has been present ≥12 months • Back Pain ≥5/10 on a VAS Pain Scale Aetna currently does offer coverage language for DPN	• Undergone Screening, Evaluation and diagnosis by a multidisciplinary team (Must Include Psychological and Physician Evaluations) • Psychological Clearance (Must be from a Psychiatrist, Psychologist, or Master of Social Work in Behavioral Health) • No untreated existing substance use disorder/s • Physician-directed Home Exercise Program, PT or OT ≥ 6 months • NSAIDs, antidepressant and anticonvulsant drugs ≥ 6 months • Oswestry Disability Index (ODI) Assessment with a score ≥ 21%	• Trial duration ≥ 5 days • Documented pain reduction ≥ 50%* • Demonstrated understanding of use of stimulator
Inoperable chronic ischemic limb pain	• Secondary to Peripheral Vascular Disease	• Undergone Screening, Evaluation and diagnosis by a multidisciplinary team (Must Include Psychological and Physician Evaluations) • Psychological Clearance (Must be from a Psychiatrist, Psychologist, or Master of Social Work in Behavioral Health) • No untreated existing substance use disorder/s • Physician-directed Home Exercise Program, PT or OT ≥ 6 months • NSAIDs, antidepressant and anticonvulsant drugs ≥ 6 months • Oswestry Disability Index (ODI) Assessment with a score ≥ 21%	• Trial duration ≥ 5 days • Documented pain reduction ≥ 50%* • Demonstrated understanding of use of stimulator

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.