



Spinal Cord Stimulation (SCS) Medical Necessity Documentation Recommendations Confirming Late or Last Resort for SCS Trials and Implants – United Healthcare and Affiliates

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

INDICATION	INDICATION ELIGIBILITY	CONSERVATIVE TREATMENT	REQUIREMENTS	IMPLANT REQUIREMENTS
Failed Back Surgery Syndrome (FBSS)	<ul style="list-style-type: none">• Refractory pain following previous lumbar surgery• Pain interferes with ADL’s• Patient is not a candidate or refuses additional back surgery	<ul style="list-style-type: none">• Continued pain after treatment ≥ than 6 months	<ul style="list-style-type: none">• No spinal cord compression history and physical examination and Imaging• No mechanical spinal instability by Imaging• No psychiatric disorder by history or controlled psychiatric disorder• No drug or alcohol misuse by history or drug and alcohol free greater than 4 weeks• No active immunosuppression• No coagulopathy or treatment for coagulopathy• No cardiac pacemaker or implantable cardioverter-defibrillator• Not pregnant• Platelet level ≥ 50,000/μL or close co-management by a hematologist	<ul style="list-style-type: none">• Trial duration ≥ 5 days• Documented pain reduction ≥ 50%*• Demonstrated understanding of use of stimulator
Chronic Intractable Back Pain without Prior Surgery	<ul style="list-style-type: none">• Back pain ≥5/10 on a valid pain scale• Back pain ≥ 6 months• Pain interferes with ADL’s• No previous spine surgery• Patient is not a candidate or refuses additional back surgery• PT/Home exercises within the past yr.	Must have Tried 1 or more of the following <ul style="list-style-type: none">• NSAID’s or acetaminophen ≥ 3 weeks• Steroid injection• Activity modification ≥ 6 weeks• Cognitive behavioral therapy	<ul style="list-style-type: none">• No spinal cord compression history and physical examination and imaging• No mechanical spinal instability by imaging• No psychiatric disorder by history or controlled psychiatric disorder• No drug or alcohol misuse by history or drug and alcohol free greater than 4 weeks• No active Immunosuppression• No coagulopathy or treatment for coagulopathy• No cardiac pacemaker or implantable cardioverter-defibrillator• Not pregnant• Platelet level ≥ 50,000/μL or close co-management by a hematologist	<ul style="list-style-type: none">• Trial duration ≥ 5 days• Documented pain reduction ≥ 50%*• Demonstrated understanding of use of stimulator
Complex Regional Pain Syndrome (CRPS)	<ul style="list-style-type: none">• Refractory pain or burningAnd must have 2 or more of the following• Allodynia or hyperalgesia• Edema• Skin color asymmetry• Sweating asymmetry• Skin temperature asymmetry• Trophic changes• Decrease ROM or motor dysfunction	<ul style="list-style-type: none">• Sympathetic block• Home exercise program, PT or OT ≥ 6 months• Antidepressant or antiepileptic drugs ≥ 4 weeks	<ul style="list-style-type: none">• No spinal cord compression history and physical examination and imaging• No mechanical spinal instability by imaging• No psychiatric disorder by history or controlled psychiatric disorder• No drug or alcohol misuse by history or drug and alcohol free greater than 4 weeks• No active immunosuppression• No coagulopathy or treatment for coagulopathy• No cardiac pacemaker or implantable cardioverter-defibrillator• Not pregnant• Platelet level ≥ 50,000/μL or close co-management by a hematologist	<ul style="list-style-type: none">• Trial duration ≥ 5 days• Documented pain reduction ≥ 50%*• Demonstrated understanding of use of stimulator
Painful Diabetic Neuropathy	<ul style="list-style-type: none">• Refractory pain or burningAnd must have 2 or more of the following• Numbness• Sensory Loss• Paresthesia	<ul style="list-style-type: none">• Home exercise program, PT or OT ≥ 6 months• Antidepressant or antiepileptic drugs ≥ 4 weeks	<ul style="list-style-type: none">• No spinal cord compression history and physical examination and imaging• No mechanical spinal instability by imaging• No psychiatric disorder by history or controlled psychiatric disorder• No drug or alcohol misuse by history or drug and alcohol free greater than 4 weeks• No active immunosuppression• No coagulopathy or treatment for coagulopathy• No cardiac pacemaker or implantable cardioverter-defibrillator• Not pregnant• Platelet level ≥ 50,000/μL or close co-management by a hematologist	<ul style="list-style-type: none">• Trial duration ≥ 1 week• 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.

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