MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Spinal Cord Stimulation/Dorsal Column Stimulation**
Policy Number	**7.01.51**
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Current Effective Date	**09/15/23**
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Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, implantation of a spinal cord stimulator (SCS) (non-high-frequency or high-frequency) has been medically proven to be effective and, therefore, is considered **medically appropriate** for treatment of patients with failed back surgery syndrome (FBSS) with intractable neuropathic leg pain, as follows:

A. A short-term trial (e.g., greater than 48 hours) of spinal cord stimulation (non-high-frequency or high-frequency [HF 10 SCS]), when **ALL** of the following criteria are met:

1. Patient has failed at least six consecutive months of physician-supervised, conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);
2. Surgical intervention is not indicated, or the patient does not wish to proceed with spinal surgery; and
3. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of an inadequately controlled behavioral health condition/issue (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain, and/or negatively impact the success of an SCS or contraindicate its placement. (*See Policy Guideline IV).*

B. Permanent implantation of an SCS (non-high-frequency or high-frequency [HF 10 SCS]), when at least a 50% reduction in pain has been demonstrated during a short-term trial of spinal cord stimulation (SCS).

II. Based upon our criteria and assessment of the peer-reviewed literature, use of a non-high-frequency dorsal column SCS has been medically proven to be effective and, therefore, is considered **medically appropriate** for treatment of patients with complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) only of the upper and lower extremities, as follows:

A. A short-term trial (e.g., greater than 48 hours) of a non-high-frequency SCS, when **ALL** the following criteria are met:
   1. Patient's diagnosis is CRPS/RSD, as evidenced by **ALL** the following:
      a. Patient has continuing pain that is disproportionate to any inciting event; and
      b. Patient reports at least one of the symptoms in **three out of four** of the following categories:
         i. Sensory: hyperesthesia; and/or
         ii. Vasomotor: temperature asymmetry, skin color changes, and/or skin color asymmetry; and/or
         iii. Sudomotor/edema: edema, sweating changes, and/or sweating asymmetry; and/or
         iv. Motor/trophic: decreased range of motion, motor dysfunction (weakness, tremor, dystonia), trophic changes (hair, nail, skin); and
      c. On physical examination, patient displays at least one of the signs in **two or more** of the following categories:
         i. Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch),
         ii. Vasomotor: evidence of temperature asymmetry, skin color changes, and/or asymmetry,
         iii. Sudomotor/edema: evidence of edema, sweating changes, and/or sweating asymmetry,
         iv. Motor/trophic: evidence of decreased range of motion, motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin); and
      d. There is/are no other medical or psychological diagnoses and/or results of relevant studies (e.g., imaging, electrodiagnostic testing, laboratory testing, etc.) that are concordant with the presenting signs and symptoms; and
      e. Limited to only the extremities and not to the head/face/neck, trunk, perineum/pelvis, or abdominal viscera; and
   2. Patient has failed at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification); and
   3. Surgical intervention is not indicated; and
   4. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of an inadequately controlled behavioral health condition/issue (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of an SCS or contraindicate its placement.

B. Permanent implantation of a non-high-frequency dorsal column SCS, when at least a 50% reduction in pain has been demonstrated during a short-term trial of spinal cord stimulation.

III. Based upon our criteria and assessment of the peer-reviewed literature, use of a non-high-frequency dorsal column SCS has been medically proven to be effective and, therefore, is considered **medically appropriate** for treatment of patients with chronic, intractable pain secondary to chronic critical limb ischemia (CLI), as follows:

A. A short-term trial (e.g., greater than 48 hours) of a non-high-frequency dorsal column SCS, when **ALL** the following criteria are met:
   1. Attestation is received from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction; and
   2. Patient has a diagnosis of CLI with Rutherford Classification *(see Description section below)* Grade II, Category 4, ischemic limb rest pain, that is characterized by **BOTH** of the following:
      a. resting ankle pressure less than 40 mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording; and
      b. toe pressure less than 30 mmHg; and
   3. Advanced imaging (i.e., angiographic imaging, computed tomography (CT) scan or magnetic resonance imaging (MRI)) demonstrates multi-level disease with absence of named vessel with flow into the foot; and
   4. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of an inadequately controlled behavioral health condition/issue (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of an SCS or contraindicate its placement.

B. Permanent implantation of a non-high-frequency dorsal column SCS, when at least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.

IV. Based upon our criteria and assessment of the peer-reviewed literature, use of a non-high-frequency dorsal column SCS has been medically proven to be effective and, therefore, is considered **medically appropriate** for treatment of patients with chronic, intractable pain secondary to chronic stable angina pectoris or myocardial ischemia, as follows:
   A. A short-term trial (e.g., greater than 48 hours) of a non-high-frequency dorsal column SCS, when **ALL** the following criteria are met:
      1. Angina pectoris is Canadian Cardiovascular Society (CCS) *(see Description section below)* functional class III or class IV; and
      2. An attestation from the patient's treating cardiologist confirms that the individual has coronary artery disease (CAD) **AND** is not a suitable candidate for a revascularization procedure; and
      3. Optimal medical treatment (OMT) that has failed to adequately improve anginal symptoms, including **ALL** the following:
         a. anti-platelet therapy; and
         b. statin and/or other lipid-lowering therapy; and
         c. anti-anginal therapy implemented to pursue a goal heart rate of 60 beats per minute; and
         d. anti-hypertensive therapy as may be indicated to pursue a goal systolic blood pressure (SBP) of less than 140 mmHG and a goal diastolic blood pressure (DBP) of less than 90 mmHG; and
      4. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of an inadequately controlled behavioral health condition/issue (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of an SCS or contraindicate its placement.

   B. Permanent implantation of a non-high-frequency dorsal column SCS, when there has been a beneficial clinical response during a short-term trial of SCS.

V. Based upon our criteria and assessment of the peer-reviewed literature, the replacement of an existing high-frequency or non-high-frequency dorsal column SCS and dorsal root ganglion (DRG) stimulator is considered **medically appropriate** when **EITHER** of the following criteria are met:
   A. The existing stimulator and/or battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty; or
   B. Revision of the electrode percutaneous array(s) or electrode plate/paddle(s) is required.

VI. Based upon our criteria and assessment of the peer-reviewed literature, replacement of a functioning non-high-frequency dorsal column SCS with a high-frequency SCS is considered **not medically necessary**.

VII. Based upon our criteria and assessment of the peer-reviewed literature, implantation of a high-frequency or non-high-frequency dorsal column SCS has not been medically proven to be effective and, therefore, is considered **investigational** for all other indications, including but not limited to:
   A. post-amputation pain (phantom limb pain);
   B. post-herpetic neuralgia;
   C. peripheral neuropathy (e.g., chronic intractable pain from diabetic sensory neuropathy);
   D. dysesthesias involving the lower extremities secondary to spinal cord injury;
   E. abdominal/pelvic visceral pain;
   F. chronic cervical, thoracic, or lumbar axial and/or radiculopathic pain without prior spinal surgery;
   G. failed cervical and/or thoracic spinal surgery with intractable neuropathic pain in arms(s) or trunk;
   H. abdominal pain related to celiac artery compression syndrome; or
   I. Neuropathic pain associated with Multiple Sclerosis.

VIII. Based upon our criteria and assessment of the peer-reviewed literature, implantation of a high-frequency SCS has not been medically proven to be effective and, therefore, is considered **investigational** for all other indications, including CRPS/RSD.

IX. Based upon our criteria and assessment of the peer-reviewed literature, dorsal root ganglion (DRG) stimulation, including replacement of a dorsal column SCS with a DRG stimulator, has not been medically proven to be effective and, therefore, is considered **investigational** for all indications, except as noted in *Policy Statement V*.

X. Based upon our criteria and assessment of the peer-reviewed literature, generator modes other than tonic-low and high-frequency (e.g., burst stimulation) has not been medically proven to be effective and, therefore, is considered **investigational.**

XI. Based upon our criteria and assessment of the peer-reviewed literature, closed loop dual-mode (high-frequency or non-high-frequency) dorsal column stimulation has not been medically proven to be effective and, therefore, is considered **investigational**.

XII. Based upon our criteria and assessment of the peer-reviewed literature, peripheral nerve field stimulation has not been medically proven to be effective and, therefore, is considered **investigational** for treatment of acute or chronic pain conditions, including the following;
   A. FBSS with intractable neuropathic leg pain;
   B. CRPS/RSD;
   C. CLI;
   D. Chronic, stable angina pectoris;
   E. Post-amputation pain (phantom limb pain);
   F. Post-herpetic neuralgia;
   G. Peripheral neuropathy; or
   H. Dysesthesias involving the lower extremities secondary to spinal cord injury.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

Refer to Corporate Medical Policy #3.01.02 Psychological Testing.

This medical policy does not address occipital nerve stimulation for chronic migraines or occipital neuralgia. In occipital nerve stimulation the neurostimulator delivers electrical impulses via insulated lead wires tunneled under the skin near the occipital nerves at the base of the head.

POLICY GUIDELINES

I. A dorsal column SCS capable of using either high-frequency or non-high-frequency stimulation (e.g., dual-mode) is considered an equally effective alternative to a non-high-frequency dorsal column SCS for the treatment of any of the medically necessary indications listed above, when the device uses non-high-frequency stimulation. A dorsal column stimulator using high-frequency is considered an equally effective alternative to non-high-frequency stimulation only for the treatment of chronic, intractable pain secondary to FBSS, as noted above.

II. The implantation of an SCS is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) need to have been tried and failed or have been judged unsuitable or contraindicated. Duration of refractory pain is six months or greater.

III. Documentation must reflect an objective measure of a 50% reduction in pain scores with a temporarily implanted electrode, prior to permanent implantation.

IV. Patients must be carefully screened, evaluated, and diagnosed by a multidisciplinary team, prior to application of these therapies. This evaluation may include a psychological evaluation to exclude any major mental disability or drug habituation that would negatively influence the outcome of the treatment. *Please to refer to Corporate Medical Policy #3.01.02 Psychological Testing.*

DESCRIPTION

Spinal cord stimulation, also known as dorsal column stimulation or neuromodulation consists of electrical stimulation of the dorsal columns by electrodes implanted in the epidural space. The neurophysiology of pain relief after treatment with an SCS is uncertain but may be related to either activation of an inhibitory system or blockage of facilitatory circuits.

Spinal cord stimulation devices consist of implantable electrodes, a receiver/transducer, and a programmable transmitter that may be worn externally or implanted. Implantation of the SCS is typically a two-step process. Initially, the electrode(s) is/are temporarily implanted in the epidural space, allowing a trial period of stimulation. This trial period will typically last for a period of three to seven days. Once treatment effectiveness has been established, the electrode(s) and receiver/transducer are permanently implanted. Successful SCS use may require extensive programming to determine the optimum levels of stimulation to provide pain relief. There are two basic types of power source. In one type, the power source (battery) can be surgically implanted. In the other, a radio-frequency receiver is implanted, and the power source is worn externally with an antenna over the receiver. Totally implantable systems are most commonly used.

Spinal cord stimulation has been utilized in a variety of refractory neuropathic pain conditions, including pain associated with FBSS, CLI, arachnoiditis, peripheral neuropathy, and CRPS. FBSS is lumbar spinal pain of unknown origin that persists despite surgical intervention or that appears after surgical intervention for spinal pain originally in the same spinal region. Surgical procedures that do not encroach into the spinal canal include interspinous/interlaminar/facet distraction and kyphoplasty/vertebroplasty surgery.

CLI is a condition in which tissue perfusion is reduced, resulting in ischemic rest pain that occurs in the toes, in the area of the metatarsal heads, or occasionally in the foot proximal to the metatarsal heads. The pain is the result of severe arterial insufficiency, which causes inadequate perfusion to the distal lower extremity.

Conte et al. (2019) reported that the lack of a target artery crossing the ankle and the absence of a suitable pedal or plantar artery target (e.g., Global Anatomic Staging System (GLASS), P2 modifier) may be considered no-option disease patterns in patients with advanced CLI (e.g., Wounds, Ischemia, and foot Infection (WIfI) stages 3 and 4). The P2 modifier in GLASS describes the circumstance in which no named artery crosses the ankle into the foot, and there is no suitable target for bypass surgery. Although technically successful endovascular interventions in the pedal arch have been reported, their durability and hemodynamic and clinical effectiveness remain unknown.

Rutherford Classification (Rutherford et al., 1997):

Grade	Category	Clinical Description	Objective Criteria
0	0	Asymptomatic- no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmHg, but at least 20 mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise and AP after exercise < 50 mmHg
II	4	Ischemic rest pain	Resting AP < 40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30 mmHg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mmHg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mmHg
	6	Major tissue loss- extending above TM level, functional foot no longer salvageable	Same as category 5
AP: ankle pressure; PVR: pulse volume recording; TM: trans metatarsal; TP: toe pressure			

CRPS is a chronic pain condition most often affecting one of the limbs (arms, legs, hands, or feet), usually after an injury or trauma to that limb. CRPS is believed to be caused by damage to, or malfunction of, the peripheral and central nervous

systems. The central nervous system is composed of the brain and spinal cord, and the peripheral nervous system involves nerve signaling from the brain and spinal cord to the rest of the body. CRPS is characterized by prolonged or excessive pain and mild or dramatic changes in skin color, temperature, and/or swelling in the affected area. There are two similar forms, called CRPS-I (previously called reflex sympathetic dystrophy syndrome) and CRPS-II (previously called causalgia), with the same symptoms and treatments. CRPS-II is the term used for patients with confirmed nerve injuries. Individuals without confirmed nerve injury are classified as having CRPS-I. People with CRPS also experience constant or intermittent changes in temperature, skin color, and swelling of the affected limb. This is due to abnormal microcirculation caused by damage to the nerves controlling blood flow and temperature. An affected arm or leg may feel warmer or cooler, compared to the opposite limb. The skin on the affected limb may change color, becoming blotchy, blue, purple, pale, or red.

Spinal cord stimulation is generally not effective in treating nociceptive pain (pain resulting from irritation, as opposed to damage to the nerves) and central deafferentation pain (pain related to central nervous system damage from a stroke or spinal cord injury).

It is recommended that candidates for spinal cord stimulation undergo a psychological evaluation prior to surgery. The purpose of the evaluation is to assess the potential role that psychological factors (e.g., anxiety, depression, underlying mental illness) may have in influencing the success of surgery and to offer appropriate recommendations with regard to psychological management.

High-frequency spinal cord stimulation, also referred to as kilohertz frequency spinal cord stimulation or HF10, provides a higher frequency than traditional SCS systems. The HF10 SCS uses low-amplitude, high-frequency, and short-duration pulses. HF10 spinal cord stimulation does not generate paresthesia and operates at a frequency of 10,000 Hz to provide pain relief, in comparison to traditional SCS systems, which operate at a frequency in the range of 40-60 Hz and do generate paresthesia. As an alternative to traditional dorsal spinal column stimulation, HF 10 spinal cord stimulation is proven safe and effective for treatment of chronic, intractable low-back and leg pain in patients with FBSS.

Peripheral nerve stimulation involves implantation of electrodes near or on a peripheral nerve, to reduce pain. Peripheral nerve field stimulation is a technology that involves placement of electrodes subcutaneously within an area of maximal pain, with the objective of stimulating a region of affected nerves to reduce pain. Depending on the targeted nerve, leads may be placed percutaneously just under the skin or via an open approach for larger deeper peripheral nerves. Similar to spinal cord stimulation, a short-term trial is required prior to permanent implantation of a generator. The use of these technologies, alone or in combination with spinal cord stimulation for the treatment of pain conditions, is under investigation.

Canadian Cardiovascular Society (CCS) Functional Classifications:

Grade	Clinical Description
I.	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous, rapid or prolonged exertion at work or recreation.
II.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair-climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.
IV.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.

RATIONALE

Traditional stimulation

Totally implantable dorsal column SCS systems are regulated by the FDA as class III pre-market-approval (PMA) devices. Several devices have received FDA PMA approval. Examples of these devices include, but are not limited to, the Precision Spinal Cord Stimulator System and the Genesis IPG System. Systems with external transmitters are regulated by the FDA as Class II Section 510(k) devices. The FDA granted Section 510(k) approval for Advanced Neuromodulation Systems to market its Renew SCS, to Medtronic to market its Spinal Cord and Peripheral Nerve Stimulation Systems, and to Micronet Medical, Inc. to market its Axxess Spinal Cord Stimulation Lead. St. Jude Medical has also received FDA approval for its Protege MRI spinal cord stimulation system.

There is sufficient evidence in the peer-reviewed literature to permit conclusions that the technology provides significant and sustained relief of pain with minimal side effects in appropriately selected patients with chronic, nonmalignant pain. Studies investigating the effectiveness of spinal cord stimulation as a treatment for patients with chronic back/extremity pain report successful management of pain, a substantial decrease in narcotic use, and an improvement in the quality of life. Studies support the use of spinal cord stimulation for patients with CRPS in the upper extremities through outcomes that demonstrate reduction in pain intensity and increased quality of life (e.g., Harke et al., 2005; Kemler et al., 2006; Kumar et al., 2011; Geurts et al., 2013).

One essential step toward the effective use of SCS devices in potential patients is a trial of the system through percutaneous lead placement. This trial will determine the effectiveness in relieving pain (greater than 50% pain relief) and improving the quality of life in patients with refractory neuropathic pain.

Literature exists to support the value of a presurgical psychological evaluation, to identify factors that may adversely impact functional outcomes after spinal cord stimulation (Doleys, 2006; Heckler et al., 2007; Celestin et al., 2009).

There is evidence to favor SCS over standard conservative treatment to improve limb salvage and clinical situations in patients with inoperable CLI (Ubbink et al., 2013 and Conte et al., 2019).

Studies found that SCS improved both the quality of life and cardiac parameters of patients with refractory angina pectoris (Pan et al., 2017).

SCS has also been investigated as a treatment for pain associated with cervical trauma or disc herniation, however further research is needed on the use of SCS treat patients with cervical trauma/disc herniation presenting with arm pain, neck pain, and/or cervicogenic headache.

<u>High-frequency stimulation</u>

Nevro (Menlo Park, Calif) gained FDA approval in May 2015 for its Senza SCS system, intended for chronic pain treatment. The device administers the company’s HF10 therapy in the trunk and/or limbs, which treats unilateral or bilateral pain related to FBSS, intractable low-back pain, and leg pain. The therapy is the only SCS therapy that is FDA-indicated to alleviate pain without paresthesia (a constant tingling sensation associated with traditional spinal cord stimulation techniques).

In July 2021, the FDA expanded the PMA indications for Nevro’s Senza SCS System when programmed to a frequency of 10k Hz to aid in the management of chronic intractable pain of the lower limb(s) associated with diabetic neuropathy. A six-month RCT (Peterson et al., 2021) of 216 patients with painful diabetic neuropathy demonstrated significant improvement in mean VAS score, neurologic examination, and health-related quality of life scores in the SCS group compared to conventional medical management alone. Longer-term studies are needed to confirm durability of effect.

<u>Burst stimulation</u>

In October 2016, the FDA approved BurstDR stimulation (St. Jude Medical), a clinician programmer application that provides intermittent "burst" stimulation for patients rather than at a constant ("tonic") rate. Burst stimulation is proposed to relieve pain with fewer paresthesia. The burst stimulation device works in conjunction with standard SCS devices. In February 2023, the FDA expanded the Indication for Use for Abbott’s Prodigy, Proclaim, and Proclaim XR SCS Systems to includ treatment of diabetic peripheral neuropathy of the lower extremities through a series of consistent stimulation pulses, called the tonic stimulation mode.

The SUNBURST (Success Using Neuromodulation with BURST) trial (Deer et al., 2018) was designed to assess the effects of Burst stimulation from St Jude Medical and enrolled 100 patients from 20 centers across the United States randomized to either receive tonic stimulation prior to Burst stimulation, or to receive Burst stimulation prior to tonic stimulation. Forty-five patients were randomized to spinal cord stimulation then burst, and the remaining 55 were randomized to burst then spinal cord stimulation. At the end of the second crossover period, patients were allowed to choose the stimulation mode they preferred and were followed for one year. The study met its primary endpoint of non-inferiority and achieved statistical significance for its pre-specified secondary endpoint of superiority demonstrating patients receiving St. Jude Medical's Burst stimulation achieved superior pain relief and greater treatment success when compared to patients receiving traditional SCS. The estimated difference in the overall visual analog scale score between burst and spinal cord stimulation was -5.1 mm (95% upper CI, -1.14 mm), demonstrating noninferiority ($p<0.001$) and superiority ($p<0.017$). The proportion of patients with a decrease in visual analog scale score of 30% or more was 60% (60/100) during burst stimulation and 51% (51/100) during spinal cord stimulation. The proportion of patients whose global impression was minimally improved, moderately improved, or very much improved was approximately 74% in both groups. The authors reported that the programming parameters were not standardized at the beginning of the study but a more standardized approach with lower amplitudes was implemented as the trial was ongoing. Trial limitations included the crossover design, which limits comparison of pain over longer periods of time, lack of blinding, and variable burst programming parameters.

Dorsal root ganglion stimulation

DRG stimulation is an emerging method of treatment for neuropathic pain. With DRG stimulation, leads are placed percutaneously into the epidural space, under fluoroscopic guidance, directly over the targeted dorsal root ganglion within the lumbar or sacral region of the spine. Similar to spinal cord stimulation, a short-term trial (i.e., greater than 48 hours) is recommended, using an external pulse generator; upon success of the trial, a permanent pulse generator may then be implanted. At this time, the evidence in the peer-reviewed scientific literature is insufficient to support long-term safety and efficacy. The use of this technology for treatment of pain conditions remains under investigation.

Closed-loop spinal cord stimulation

A novel spinal cord stimulation system, the Evoke Spinal Cord Stimulation (SCS) System, provides the first in vivo, real-time, continuous objective measure of spinal cord activation in response to therapy via recorded evoked compound action potentials (ECAPs) in patients during daily use. The Evoke SCS System is an implanted, rechargeable spinal cord stimulation system intended to treat long-term (chronic) pain in the trunk or limbs that are difficult to manage (intractable) and received Federal and Drug Administration (FDA) approval on February 28, 2022. The system is designed to operate in either of two modes: an evoked compound action potential (ECAP) controlled closed-loop stimulation mode or an open-loop (fixed output) stimulation mode. The open-loop stimulation mode is equivalent to that of traditional SCS, and the closed-loop purportedly can provide real-time measurement and automatic adjustment of the strength of the stimulation based on the reading, recording, and response to the ECAP.

Mekhail et al. (2020 & 2022) designed a study to examine pain relief and the extent of spinal cord activation with evoked compound action potentials (ECAPs)-controlled closed-loop versus fixed-output, open-loop spinal cord stimulation for the treatment of chronic back and leg pain. This study is the first to record in-vivo human spinal cord electrophysiology in both stimulation modes and reported that more closed-loop group patients as responders (≥50% reduction) in overall pain 53 of 67 [79.1%] versus 36 of 67 [53.7%] in the open-loop group.

Brooker et al. (2021) reported research findings from the Avalon study, which was also designed to investigate the use of the first closed-loop SCS system in patients with chronic pain. This is a prospective, multicenter, single-arm study where 50 patients were enrolled and followed at one, three, six, 12, 15, 18, 21, and 24 months post permanent implantation of the Evoke SCS System. Although the reported 24-month results support the 12-month results of both this Avalon study and the Evoke study, the study has limitations, and the technology remains under investigation.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
63650	Percutaneous implantation of neurostimulator electrode array; epidural
63655	Laminectomy for implantation neurostimulator electrode, plate/paddle; epidural
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy when performed
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s) including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
95970-95972	Neurostimulator programming and analysis (code range)

HCPCS Codes

Code	Description
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1826 **(E/I)**	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system *(effective 01/01/2023)*
C1827	Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller *(effective 01/01/2023)*
L8679	Implantable neurostimulator pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

Code	Description
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD10 Codes

Code	Description
Multiple diagnosis codes	

REFERENCES

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*Key Article

KEY WORDS

Burst stimulation, Dorsal column, Dorsal root ganglion, High-frequency neurostimulation, Neuromodulation, Neurostimulation, Wireless neurostimulation, Closed-loop SCS

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for electrical nerve stimulators that includes dorsal column stimulators. Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=240&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&] accessed 04/14/23.