Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Neurostimulation, Spinal Cord/Dorsal Column and Dorsal Root Ganglion

Policy Number: PG0253
Last Review: 04/11/2022

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

X Professional
_ Facility

DESCRIPTION:

Spinal cord stimulators (SCS), also known as dorsal column stimulators (DCS) involves the use of low-voltage electrical current stimulation of spinal nerves using electrodes implanted in the epidural space of the spinal column. SCS was developed as a treatment based on the gate control theory of pain, which suggests that pain signaling could be inhibited by activation of large diameter collateral myelinated Aβ fibers in the dorsal columns. The objectives of treatment are to minimize the frequency, intensity and duration of pain; enhance physical activity; and decrease the need for pain medication. The use of SCS/DCS for controlling chronic low back pain is a non-destructive, reversible procedure, and it is therefore an attractive alternative for patients who may be facing or have already experienced neuroablative procedures, or habituating opioid medications. There is some evidence from studies of low to moderate quality that SCS/DCS can reduce chronic, refractory, neuropathic pain, and may improve quality of life in patients with failed back surgery syndrome, and complex regional pain syndrome.

A technique with a different neural target than dorsal column stimulation is dorsal root ganglion stimulation. Dorsal root ganglia are located in the epidural space between spinal nerves and the spinal cord on the posterior root in a minimal amount of cerebrospinal fluid, amenable to epidural access. Electrodes are placed through the intraspinal epidural space in contact with the sensory dorsal root ganglia. Electrical fields are generated that can selectively stimulate different parts of the dorsal root ganglia. This is intended to allow focusing of stimulation onto specific nerve roots or parts of nerve roots.

Examples of SCS include, but may not be limited to, Algovita, Precision Novi SCS System, Precision Plus SCS System and Precision Spectra System. The Precision Montage MRI SCS, PrimeAdvanced SureScan, RestoreAdvanced SureScan, RestoreSensor SureScan and RestoreUltra SureScan are examples of SCS that have been approved by the US Food & Drug Administration (FDA) for use in a magnetic resonance imaging (MRI) scanner.

Examples of DCS include, but are not limited to, Eon, EonC, Eon Mini, Genesis IPG System, Intellis, Itrel4, Precision Plus SCS System, Precision Spectra, PrimeAdvanced Neurostimulator, Protégé, Restore,

RestoreAdvanced, RestorePrime, Restore Sensor, RestoreUltra, Specify, Synergy, Vanta, Vectris, or WaveWriter Alpha). High-frequency devices include but are not limited to Senza or burst (Burstdr).

Spinal cord stimulators has also been shown to be effective in the treatment of patients with angina pectoris who fail to respond to standard pharmacotherapies and are not candidates for surgical interventions.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount Commercial Insurance Plans and Paramount Advantage Medicaid
Spinal Cord/Dorsal Column and Dorsal Root Ganglion (63650, 63655, & 63685) neurostimulator electrode trial insertion and permanent placement requires prior authorization. Additionally, effective 10/1/2019 neurostimulator electrode revision (63663 & 63664) requires prior authorization.

Elite (Medicare Advantage) Plans
Spinal Cord/Dorsal Column and Dorsal Root Ganglion (63650, 63655, & 63685) neurostimulator electrode trial insertion and permanent placement requires prior authorization. Additionally, effective 01/01/2020 neurostimulator electrode revision (63663 & 63664) requires prior authorization.

[Note: If the device implantation is approved, electronic analysis is also covered (CPTs 95970-95972), no prior authorization required.]

COVERAGE CRITERIA:
Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Medical Indications: Spinal cord/dorsal column and dorsal root ganglion neurostimulation must satisfy one of the following: 1 or 2

1. Spinal cord/dorsal column stimulation (SCS/DCS) for any of the following: a – d
    a. Failed back surgery syndrome (FBSS) with low back pain and significant radicular pain; or
        FBSS is lumbar spinal pain of unknown origin persisting after surgical intervention or first appearing after surgical intervention for spinal pain originally in the same location. May also be called post-laminectomy syndrome.

    b. Cervical/ low back complex regional pain syndrome (CRPS); or
        CRPS describes painful conditions characterized by ongoing, spontaneous and/or evoked, regional pain that seems out of proportion to known trauma or causative lesion. Previous names for CRPS include reflex sympathetic dystrophy and causalgia. Two subtypes of CRPS have been recognized:
            - Type I describes cases without evidence of peripheral nerve injury
            - Type II describes cases in which peripheral nerve injury is present

    c. Inoperable chronic ischemic limb pain, secondary to peripheral vascular disease (when the member cannot undergo revascularization or when revascularization has failed to relieve painful symptoms and the pain has not responded to medical management); or

    d. Last resort treatment of chronic, intractable neuropathic pain:
        - lumbosacral arachnoiditis and radiculopathies (Presence of arachnoiditis is usually documented by presence of high levels of proteins in the CSF and/or by myelography or MRI.),
        - phantom limb/stump pain,
        - peripheral neuropathy,
        - diabetic peripheral neuropathy (DPN),
        - post-herpetic neuralgia,
        - intercostal neuralgia,

- cauda equina injury,
- incomplete spinal cord injury,
- plexopathy

And must satisfy both of the following: 1 or 2

1. Pain is characterized as moderate to severe and present for ≥ 3 months, (5 or more on a 10-point VAS scale); and

1. Other treatment modalities (pharmacological, surgical, physical or psychological therapies) have been tried and did not prove satisfactory or are judged unsuitable or contraindicated for the given patient (Pharmacological treatments used to manage neuropathic pain include antidepressants (especially tricyclic antidepressants), anticonvulsants (e.g., gabapentin, pregabalin), opioids (e.g., morphine, oxycodone, tramadol), N-methyl-D-aspartate receptor antagonists, topical agents (e.g., capsaicin or lidocaine), cannabinoids, and botulinum toxin.)

2. Dorsal root ganglion stimulation (eg, Axium Neurostimulator System) for the treatment of moderate to severe (5 or more on a 10-point VAS scale) chronic intractable pain of the lower limb(s) in members with CRPS types I or II.

Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other indications due to insufficient evidence of efficacy.

Percutaneous (temporary) spinal cord/dorsal column or dorsal root ganglion stimulator trial period must be initiated first, when medical indications criteria above is met, and ALL of the following is meet: 1-3

1. Documentation of thorough diagnostic testing completed, indicating an objective basis for the pain complaint including;
   - a pre-trial assessment of function, using a tools such as, but not limited to, the Oswestry Disability Questionnaire, the Roland-Morris Disability Questionnaire, and the physical health scales of the Medical Outcomes Study 36-Item Short-Form Health Survey; and
   - Spinal cord compression excluded by history and physical examination and imaging; and
   - Pain is not associated with malignancy; and
   - No pacemaker or other medical contraindications (i.e. sepsis or coagulopathy); and

3. Failure of 6 months of conservative treatment (such as, but not limited to, pharmacotherapy, psychotherapy, and physical therapy), as defined by unsatisfactory pain control; and

3 Documentation of a mental health evaluation within 6 months of a stimulator trial request (such as, but not limited to, face-to-face assessment with or without psychological questionnaires and/or psychological testing) by a mental health provider revealing no evidence of existing behavioral health problems (such as, but not limited to, alcohol or drug dependence, depression, and psychosis) that are inadequately controlled.

Permanent implanted spinal cord/dorsal column or dorsal root ganglion stimulator may be initiated following a positive response to a percutaneous trial as demonstrated by ALL of the following: 1-4

4. Trial period is ≥ 3 days; and

5. Greater than or equal to 50% reduction in pain; and

6. Improvement in function (must submit documentation of pre-and post-trial assessment scores from assessment tools such as, but not limited to, the Oswestry Disability Questionnaire, the

Roland-Morris Disability Questionnaire and the physical health scales of the Medical Outcomes Study 36-Item Short-Form Health Survey; and

7. Member demonstrated understanding of use of stimulator during trial period.

Spinal cord stimulators (SCS) are medically indicated for management of intractable angina in members who are not surgical candidates and whose pain is unresponsive to all standard therapies and whom met ALL of the following indications; 1-9

1. Documentation supports angiographic coronary artery disease and is not candidate for revascularization procedures or continued angina after percutaneous coronary intervention or coronary artery bypass graft; and

2. Optimal pharmacology therapy for at least one month that includes the maximal tolerated dose of at least 2 of the following:

    a. Long-acting nitrates;
    b. Beta-adrenergic blockers;
    c. Calcium channel antagonists; and

3. Member's angina pectoris is New York Heart Association (NYHA) Functional Class III (patients are comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or angina pain) or Class IV (symptoms of cardiac insufficiency or angina are present at rest; symptoms are increased with physical activity); and

4. Pain is chronic, refractory, and interferes with ADLs; and

5. Has demonstrated cognitive ability to manage stimulator; and

6. Psychological evaluation and clearance by a qualified mental health professional reveals no evidence of an inadequately controlled mental health problem; and

7. No untreated, existing drug or alcohol dependency for a minimum of 60 days prior to request, as confirmed by lab testing; and

8. Reversible ischemia is documented by symptom-limited treadmill exercise test; and

9. A percutaneous (temporary) spinal cord stimulator trial period experienced significant pain reduction (50 % or more). (A trial of percutaneous spinal stimulation is considered medically necessary for members who meet the above-listed criteria, in order to predict whether a dorsal column stimulator will induce significant pain relief)

Replacement of standard or high-frequency spinal cord stimulator battery/generator, lead or electrode, or patient programmer may be considered medically necessary for a member that meets the above medical necessity criteria and the existing stimulator, battery/generator, lead or electrode, or patient programmer are/is no longer under warranty and cannot be repaired.

Removal or revision of a standard or high frequency spinal cord stimulator device may be considered medically

necessary for migration of the lead(s), loss of effectiveness, and intolerance by the individual, infection, painful generator site, development of neurological deficits or the need for an MRI study.

Replacement or upgrade of existing, properly functioning equipment is considered not medically necessary. Replacement of a functioning standard dorsal column stimulator with a high-frequency or burst dorsal column stimulator is considered not medically necessary.

Exclusions: may not be all-inclusive:
Spinal cord/dorsal column and dorsal root ganglion neurostimulation for the treatment of pain associated with conditions/diseases including, but not limited to, the following are considered experimental/investigational, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Cervical spine for the treatment of any condition not listed under Indications that are covered, including, but not limited to, neck and arm pain caused by cervical trauma, cervical disc herniation, failed cervical spine surgery syndrome or cervicogenic headache
- Cervical dorsal column stimulation is considered experimental and investigational for the treatment of members with cervical trauma, disc herniation, essential tremor, failed cervical spine surgery syndrome presenting with arm pain, neck pain, cervicogenic headache, gliomas, migraine, radiation-induced brain injury, stroke, trigeminal neuropathy, or any other indication (other than CRPS) because its effectiveness for these indications has not been established.
- Central deafferentation pain (pain related to central nervous system damage from stroke or spinal cord surgery)
- Chronic pain from malignancy (cancer)
- Dorsal root ganglion neurostimulation for any non-CRPS lower extremity indication
- Dorsal root ganglion neurostimulation in patients with CRPS lower extremity who currently have a spinal cord stimulator or who have previously failed spinal cord stimulation therapy
- Heart failure
- Fibromyalgia
- Peripheral vascular disease
- Plexus lesions caused by trauma or malignancy
- Multiple sclerosis and spasticity disorders
- Paraplegia and other spinal cord lesions
- Peripheral nerve injuries or deafferentation, which includes neuropathy due to injuries, surgery, entrapment or scars
- Post-amputation pain
- Post herpetic neuralgia
- Simultaneous placement of a dorsal column and dorsal root ganglion stimulator
- Spasticity disorders
- Treatment of critical limb ischemia to forestall amputation

Paramount considers the following as contraindications to spinal cord stimulation: pregnancy, uncontrolled psychiatric disorder, inability to comply with therapy, persistent local or systemic infection, patient has cardiac pacemaker or implantable defibrillator, coagulopathy, anticoagulant or antiplatelet therapy, or thrombocytopenia (ie, platelet count of less than 75,000/mm3 (75 x109 /L)).

Paramount considers the concurrent use of 2 SCS/DCS column stimulators for the treatment of complex regional pain syndrome or any other indications experimental and investigational because the effectiveness of this approach has not been established.

Paramount considers the combined use of SCS/DCS and dorsal root ganglion stimulation for the treatment of complex regional pain syndrome or any other indications experimental and investigational because the effectiveness of this approach has not been established.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, 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	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
HCPCS CODES	
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each (up to 16 units allowed if dual lead procedure performed)
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
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 implanted neurostimulator (replacement only)
L8695	External recharging system for battery (external) for use with implantable neurostimulator (replacement only)

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/15/2009

Date	Explanation & Changes
10/24/14	• Removed deleted code 63660 • Added codes 63661, 63662, 63663, 63664, C1767, & C1816 • SCS (63650, 63655) will now require prior authorization following InterQual criteria for HMO, Individual Marketplace, Elite, & Advantage • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
1/22/16	• Prior authorization now required for PPO • Added code 63685 to require prior authorization for all product lines • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
1/27/17	• Removed deleted code 95973 effective 12/31/16 • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
8/14/19	• Specific coverage criteria documentation added to the policy, InterQual® criteria sets • Procedures 63663 and 63664 added to the procedures requiring a prior authorization for all product lines, except Elite, effective 10/1/2019
12/01/19	• Medical Policy revised to include the Elite Product requiring a prior authorization as of 1/1/2020
12/18/2020	• Medical policy placed on the new Paramount Medical Policy Format
04/11/2022	• Changed medical policy title from Spinal Cord Stimulation to Neurostimulation, Spinal Cord/Dorsal Column and Dorsal Root Ganglion • Policy reviewed and updated to reflect most current clinical evidence • Updated documentation to include diabetic peripheral neuropathy (DPN) as a medical indication for spinal cord/dorsal column stimulation (SCS/DCS)
02/16/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/29/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
03/06/2024	• Medical policy placed on the new Paramount Medical Policy Format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to
https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/ Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review