02-61000-05

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Subject: Spinal Cord and Dorsal Root Ganglion Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Spinal cord stimulation (SCS) delivers low-voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain; this is achieved through a surgically implanted SCS device, which comes equipped with a radiofrequency receiver. The neurostimulator device is also issued with a standard power source (battery) that can be implanted or worn externally. Other neurostimulators target the dorsal root ganglion.

SCS devices consist of several components: (1) the lead that delivers the electrical stimulation to the spinal cord; (2) an extension wire that conducts the electrical stimulation from the power source to the lead; and (3) a power source that generates the electricity. The lead may incorporate from 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns. There are 2 basic types of power source: one type, the power source (battery), can be surgically implanted or worn externally with an antenna over the receiver; the other, a radiofrequency receiver, is implanted. Totally implantable systems are most commonly used.

Traditional SCS devices use electrical stimulation with a frequency of 100 to 1000 Hz. In 2015, an SCS device, using a higher frequency (10,000 Hz) than predicate devices, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. High-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of SCS. In 2016, FDA approved a clinician programmer application that allows an SCS device to provide stimulation in bursts rather than at a constant rate. Burst stimulation is proposed to relieve pain with fewer paresthesias. The burst stimulation device works in conjunction with standard SCS devices. With the newly approved app, stimulation is provided in five 500-Hz burst spikes at a rate of 40 Hz, with a pulse width of 1 ms.

Other neurostimulators target the dorsal root ganglion (DRG). Dorsal root ganglia consists of sensory cell bodies that transmit input from the peripheral nervous system to the central nervous system, and play a role in neuropathic pain perception. 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. Two systems targeting the dorsal root ganglion have received approval from the FDA.

POSITION STATEMENT:

Temporarily implanted standard or high-frequency spinal cord stimulator or dorsal root ganglion stimulator **meets the definition of medical necessity** for the treatment of severe and chronic, intractable neuropathic pain of the trunk or limbs when **ALL** of the following criteria are met:

- The treatment is used as a last resort; **AND**
- Other treatment modalities (pharmacologic, surgical, physical, psychological) have been tried and failed **OR** the treatment modalities are judged to be unsuitable or contraindicated; **AND**
- Pain is neuropathic in nature i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to, failed back surgery syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy, and painful diabetic neuropathy. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury); **AND**
- Psychological evaluation was obtained and documentation clearly states the pain is not psychological in origin and/or no evidence of an uncontrolled mental health problem (e.g., alcohol or drug dependence, depression, psychosis).

Permanent implanted standard or high-frequency spinal cord stimulator or dorsal root ganglion stimulator **meets the definition of medical necessity** for the treatment of severe and chronic, intractable neuropathic pain of the trunk or limbs when **ALL** of the following criteria are met:

- All criteria for temporarily implanted stimulator are met **AND**
- Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation.

Spinal cord stimulation and dorsal root ganglion neurostimulation is considered **experimental or investigational** for all other indications including, but not limited to, treatment of critical limb ischemia to forestall amputation, treatment of refractory angina pectoris, heart failure, and cancer-related pain. There is insufficient evidence to conclude that spinal cord stimulation improves net health outcomes.

BILLING/CODING INFORMATION

CPT Coding:

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/transmitter (eg, contact group[s],interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter,without programming
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s],interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS Coding:

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
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 battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD-10 Diagnosis Codes That Support Medical Necessity:

G56.40	Causalgia of unspecified upper limb
G56.41	Causalgia of right upper limb
G56.42	Causalgia of left upper limb
G56.43	Causalgia of bilateral upper limbs
G57.70	Causalgia of unspecified lower limb
G57.71	Causalgia of right lower limb
G57.72	Causalgia of left lower limb
G57.73	Causalgia of bilateral lower limbs
G89.0 – G89.4	Pain, not elsewhere classified
G90.50 – G90.59	Complex regional pain syndrome I (CRPS I)
M25.50 – M25.579	Pain in joint
M54.10 – M54.18	Radiculopathy
M54.30 – M54.32	Sciatica
M54.40 – M54.42	Lumbago with sciatica
M54.5	Low back pain
M54.6	Pain in thoracic spine
M54.81 – M54.9	Dorsalgia
M79.10 - M79.18	Myalgia
M79.601 – M79.676	Pain in limb, hand, foot, fingers and toes

REIMBURSEMENT INFORMATION:

Reimbursement for the revision or removal of a dorsal root ganglion or spinal cord neurostimulator is made only if the implantation procedure was initially allowed and the existing stimulator, battery, or generator is malfunctioning and cannot be repaired.

The following information is required documentation to support medical necessity: physician history and physical, physician progress notes including demonstration of pain relief with temporary stimulator, documentation of other treatment modalities (pharmacological, surgical, therapy), treatment plan including narrative, radiology study reports, and physician operative report.

LOINC Codes:

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Radiology	18726-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician operative report	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Treatment plan, plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Physical therapy initial assessment	18735-1	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Physical therapy progress note	11508-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Current, discharge, or administered medications	34483-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Electrical Nerve Stimulators (160.7) located at cms.gov.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

Deep Brain Stimulation and Responsive Neurostimulation, 02-61000-24

OTHER

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 05/25/23.

GUIDELINE UPDATE INFORMATION:

09/15/02	Medical Coverage Guideline Reformatted.
01/01/04	Annual HCPCS coding update.
10/15/04	Review and revision to guideline; consisting of updated references, removed information about intracranial neurostimulation and moved information to Deep Brain Stimulation MCG, added information to description section, added additional information to When Services are Covered section, and changed name from Central Nervous Stimulators to Spinal Cord Stimulation.
01/01/05	Annual HCPCS coding update: consisting of the revision of 63685 and the addition of 95970, 95971, 95972 and 95973.
10/15/05	Review and revision of guideline; consisting of updated references.
01/01/06	Annual HCPCS coding update: consisting of the deletion of E0752, E0756, E0757, E0758 and the addition of L8680, L8681, L8682, L8683, L8685, L8687, L8688, and L8689.
10/15/06	Review and revision of guideline consisting of updated references.
01/01/07	Annual HCPCS coding update: consisting of the revision of L8689 and the addition of L8695.
07/15/07	Annual review, current coverage maintained, guideline reformatted, references updated.
10/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: revised descriptor for codes L8681, L8689, and L8695.
09/15/09	Annual review: maintained position statements, description section, and references updated.
01/01/10	Annual HCPCS coding update: added codes 63661 – 63664; deleted code 63660.
07/15/10	Annual review: position statements maintained and references updated.
10/15/10	Revision: formatting changes.
10/01/11	Revision: formatting changes.
01/01/12	Annual HCPCS update. Revised descriptor for codes 95970-95973.
01/01/14	Annual HCPCS update. Added code L8679. Program Exceptions section updated.
03/15/14	Review; updated position statement, Program Exceptions, and references; formatting changes.
01/01/15	Annual HCPCS/CPT update. Revised code 95972.
03/15/15	Annual review; investigational position statement and references updated; formatting changes.
01/01/16	Annual HCPCS/CPT update; code 95972 revised, code 95973 deleted.
07/15/16	Revision; description, position statement section and references updated; formatting changes.
10/01/16	ICD-10 coding update; codes G56.43 & G57.73 added. Revision; formatting changes.
01/01/17	Annual CPT/HCPCS update. Revised 95972.

06/15/17	Revision; High-frequency spinal cord stimulation added to position statements; investigational statement for wireless injectable dorsal root ganglion neurostimulation added; description section and references updated.
09/15/17	Revision; Dorsal root ganglion position statement updated; guideline title and references updated.
10/01/18	ICD-10 coding update; added codes M79.10-M79.18; deleted code M79.1.
01/01/19	Annual CPT/HCPCS coding update. Revised codes 95970-95972.
06/15/19	Review; DRG stimulation positon statements, reimbursement section, references updated.
08/15/21	Review; Position statements maintained; references updated.
06/15/23	Review: *Painful diabetic neuropathy* added to list of indications in pain criteria; references updated.