Spinal Cord Stimulation
Clinical Coverage Criteria

Overview

Dorsal column stimulation, also known as spinal cord stimulation (SCS) involves the implantation of a spinal cord stimulator for the relief of chronic intractable pain. SCS is best suited for neuropathic pain, but may have some limited value in other types of nociceptive severe, intractable pain. Selection of patients for implantation of SCS is critical to success of this therapy. SCS therapy should be considered as a late option after more conservative attempts, such as medications, physical therapy, psychological therapy or other modalities have been tried. SCS consists of a short trial (e.g., 5-14 days) with percutaneous implantation of neurostimulator electrode(s) for assessing a patient's suitability for treatment with a permanent surgically implanted nerve stimulator. Performance and documentation of an effective trial is required for permanent nerve stimulation. A successful trial should be associated with at least a 50% reduction of target pain, or 50% reduction of analgesic medications, and show some element of functional improvement.

A large number of neurostimulator devices used for spinal cord stimulation (SCS), have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process.

Policy

This Policy applies to the following Fallon Health products:
☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Prior authorization is required for spinal cord stimulation.

Medicare Advantage
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for spinal cord stimulation. Medicare has an NCD for Electrical Nerve Stimulators (160.7). The implantation of a spinal cord stimulator may be covered for the treatment of chronic intractable pain. National Government Services, Inc. doesn't have an LCD or LCA for spinal cord stimulation (MCD search 07/22/2024).

Coverage criteria for spinal cord stimulation are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

Link: **NCD Electrical Nerve Stimulators (160.7)**

Indications and Limitations of Coverage

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators
Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch.

Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in §160.7.1, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators)
The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. Types of Implantations
There are two types of implantations covered by this instruction:
- Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.
- Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. Conditions for Coverage
No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:
- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
- With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
- Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy item c) must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making

medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for spinal cord stimulation (MassHealth website search 07/22/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Effective for dates of service on or after August 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for spinal cord stimulation.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:
- InterQual® CP:Procedures, Spinal Cord Stimulator Temporary Electrode Trial
- InterQual® CP:Procedures, Spinal Cord Stimulator (SCS) Insertion

The medical record must include documentation of the diagnosis, symptoms and provider-directed treatments attempted before the decision to proceed to a spinal cord stimulator.

Only plan members who experience a successful trial should proceed to permanent implantation. Accurate selection should lead to most plan members going on to receive permanent implants. All trials which proceed to permanent implantation must have adequate documentation in the medical record to support this decision.

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Exclusions

- Spinal cord stimulation is considered experimental or investigational for all other indications including, but not limited to, the treatment of cancer-related pain.
- A repeat trial is not medically necessary unless there are extenuating circumstances that lead to trial failure.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Code	Description
Temporary trial	
63650	Percutaneous implantation of neurostimulator electrode array, epidural
Lead implantation	
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrode plate/paddle; epidural
Generator implantation or replacement	
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
Removal of leads	
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
Revision or replacement of leads	
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
Revision or removal of generator	
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
Analysis and programming	
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

Device C-codes

For hospital outpatient claims reimbursed under Medicare OPPS payment methodology, C-Codes are required. For ASC claims reimbursed under Medicare methodology, C-Codes are not reported for

packaged items, yet may be reported for non-packaged items such as items with transitional pass-through status. C1826 has Medicare pass transitional pass-through status effective 1/1/23-12/31/25.

Code	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator, test kit (implantable)
C1787	Patient programmer, neurostimulator

Device L-codes

Code	Description
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
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

References

1. Medicare National Coverage Determination for Electrical Nerve Stimulators (160.7). Effective 08/07/1995. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Accessed 07/22/2024.
2. Medtronic. 2024 Coding and Payment Guide. Spinal Cord Stimulation. Available at: https://www.medtronic.com/content/dam/medtronic-com/professional/documents/spinal-cord-stimulation-reimbursement-guide.pdf. Accessed 07/22/2024.

Policy history

Origination date: 01/01/2014

Approval(s): Technology Assessment Committee 10/23/2013 (adopted InterQual Criteria), 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review); 05/27/2020 (adopted Fallon Health criteria), 02/10/2022 (added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 07/23/2024 (annual review, updated Medicare Advantage under Policy section, adopted InterQual Criteria, updated Coding).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-

funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.