

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., 3-14 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.

Policy

This Policy applies to the following Fallon Health products:
Commercial
Medicare Advantage
MassHealth ACO
NaviCare
PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Electrical Nerve Stimulators (160.7). National Government Services, Inc. doesn't have an LCD or LCA for spinal cord stimulation (MCD search 02/10/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

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.

Prior authorization is required.

Fallon Health Clinical Coverage Criteria

Fallon Health follows Medicare's National Coverage Determination (NCD) criteria for dorsal column (spinal cord) stimulation for all plan members (NCD 160.7).

NCD link: Electrical Nerve Stimulators (160.7)

Per NCD 160.7, spinal cord stimulation (SCS) is covered when ALL of the following criteria are met:

- a. The implantation of the stimulator is used only as a late resort (if not a last resort) for plan members with chronic intractable pain;
- b. 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 member;
- c. The member has 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 member (including that required to satisfy item c) must be available; and
- e. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Selection of patients for implantation of spinal cord stimulators is critical to success of this therapy. SCS may be covered for the relief of chronic intractable pain under the following circumstances:

- To treat chronic pain caused by lumbosacral arachnoiditis that has not responded to medical management including physical therapy. (Presence of arachnoiditis is usually documented by presence of high levels of proteins in the Cerebrospinal Fluid (CSF) and/or by myelography or Magnetic Resonance Imaging (MRI)
- To treat intractable pain caused by nerve root injuries, post-surgical or post-traumatic including that of
 post-laminectomy syndrome (failed back syndrome).
- To treat intractable pain caused by complex regional pain syndrome I & II.
- To treat intractable pain caused by phantom limb syndrome that has not responded to medical management.
- To treat intractable pain caused by end-stage peripheral vascular disease, when the patient cannot undergo revascularization or when revascularization has failed to relieve painful symptoms and the pain has not responded to medical management.
- To treat intractable pain caused by post-herpetic neuralgia.
- To treat intractable pain caused by plexopathy.
- To treat intractable pain caused by intercostal neuralgia that did not respond to medical management and nerve blocks.
- To treat intractable pain caused by cauda equina injury.
- To treat intractable pain caused by incomplete spinal cord injury.

The medical record should include the elements leading to the diagnosis and the therapies tried before the decision to proceed to the use of a spinal cord stimulator. Plan members being selected for a trial must not have active substance abuse issues.

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. 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.

Exclusions

- SCS is considered experimental or investigational for all other indications including, but not limited to, treatment for refractory angina pectoris and 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
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of 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

References

1. Medicare National Coverage Determination for Electrical Nerve Stimulators (160.7). Effective 08/07/1995. Available at: <u>https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx</u>. Accessed 02/10/2022.

Policy history

Origination date: Approval(s):	01/01/2014 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).

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.