



Medicare Part C Medical Coverage Policy

Electrical Stimulators- Spinal Cord

Origination: June 30, 1988
Review Date December 15, 2021
Next Review: December, 2023

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Spinal Cord Stimulation (SCS) sometimes referred to as Central Nervous System Stimulators (Dorsal Column) delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to suppress pain in specific areas for patients with a variety of chronic pain disorders. The Spinal Cord Stimulation (SCS) device is connected by leads to a surgically implanted receiver. Signals transmitted to the electrodes from either an external or implanted power source excite the large sensory fibers in the spinal cord and block pain signals from reaching the brain.

POLICY STATEMENT

Coverage will be provided for spinal cord stimulators when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE:

A. Preauthorization by the Plan is required prior to the stimulator being dispensed by the vendor;

AND

B. A documented care plan indicating the stimulator use and expected outcome must be submitted by the physician;

AND

C. Spinal Cord Stimulators (SCS)/Central Nervous System Stimulators (Dorsal Column) are covered when ALL of the following criteria are met:

1. Therapy consists of a short trial with a percutaneous implantation of neurostimulator electrode(s) in the epidural space for assessing a member's suitability for ongoing treatment with a permanent surgically implanted nerve stimulator. Performance and documentation of an effective trial is required for consideration of permanent nerve stimulation; **and**
2. The implantation of the stimulator is used only as a late or last resort for patients with chronic intractable pain; **and**
3. Other treatment modalities (pharmacologic, surgical, physical/and psychological therapies) have been tried and did not prove satisfactory; were judged unsuitable, or were contraindicated for the patient; **and**
4. Member has undergone appropriate psychological screening and diagnosis by a multidisciplinary team before implantation; to include patient education, discussion and disclosure including an extensive discussion of the risk and benefits of therapy; **and**
5. All the facilities, equipment, and professional support personnel required for the proper diagnosis, treatment, training, and follow-up of the patient are available; **and**
6. All trials which proceed to permanent implantation should demonstrate adequate documentation to support the decision. A successful trial should be associated with 50% reduction of target pain or 50% reduction of analgesic medications and show some element of functional improvement. (Patients with reflex sympathetic dystrophy may show lower levels of improvement since it takes longer periods for improvement than the typical one to two weeks).

WHEN COVERAGE WILL NOT BE APPROVED

Spinal Cord Stimulation will not be approved if all the criteria above are not met.

Member must not have active substance abuse issues to be selected for a trial.

SPECIAL NOTE:

If a trial fails, a repeat trial is not appropriate unless there are extenuating circumstances that lead to trial failure. A repeat trial will require Medical Director Review.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee that it will be reimbursed.

Applicable codes: 63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688, L8679, L8689.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

References:

1. Medicare National Coverage Determination for Electrical Nerve Stimulators (160.7); Effective date: 8/7/1995, reviewed 10/03/2003, accessed via Internet site www.cms.gov viewed on 12/2/21.
2. Medicare Local Coverage Determination for Spinal Cord Stimulators for Chronic Pain – Palmetto GBA Part B; L37632; Effective Date: 11/19/2015, accessed via www.cms.gov 12/2/21.
3. Medicare Local Coverage Determination for Tumor Treatment Field Therapy (TTFT) (L34823) - CGS Administrators; Effective 10/01/2015; viewed via www.cms.gov; viewed 12/2/21.
4. US Department of H&HS; www.FDA.gov; Medical Devices: NovoTTF-100A System-P100034.

Policy Implementation/Update Information:

Revision Date: January 7, 2002; February 23, 2005

Revision Date: November 30, 2006: Clarified severe angina as class III or IV on NYHA classification scale and clarified that members can not have any history of drug addiction. Current codes added.

Revision Date: September 2009: No changes proposed to the review criteria. Formatting and minor wording changes only.

Revision Date: October 28, 2010 Removed code 63660 and replaced it with 63661, removed items a-d, under #2; "When all the following criteria are met", removed items #1-6; "When Coverage Will Not Be Approved" to remain current with CMS guidelines.

Revision Date: June 21, 2011 Remove item 6 from Indication for Coverage section since it is not consistent with CMS guidelines.

Revision Date: 02/20/2013; Edits include "and psychological therapies to #2, patient education including risk and benefits to #3, Added there must not be active substance abuse issues to be selected for a trail; Clarified #5 in regard to RSD, Added conditions of which Dorsal Stimulation may be covered for pain.

Revision Date: 02/19/2014; Annual Review; Revised with minor edits for clarification. Added a special note regarding Tumor Transmitting Fields to be reviewed case by case by the medical director. Revised codes.

Revision Date: 08/20/2014; Added a special note that Tumor Treatment Field Therapy (TTFT) is not covered per the Palmetto LCD: L34655.

Revision Date: 11/24/2015: Description of Procedure or Service – incorporated reference for Central Nervous System Stimulators (Dorsal Column); Indications for Coverage- added item A – referencing both Spinal Cord Stimulators and Central Nervous System Stimulators per both LCD and NCD, added item #1 to include a trial of a spinal cord stimulator is required prior to permanent implantation, updated items #4 and #6 per LCD and NCD; Special Notes - additional language related to trials and removed criteria reference for Dorsal Stimulators, Code section - removed code L8680 as it is no longer considered valid for Medicare and added codes per LCD; updated reference section.

Revision Date: 12/20/2017: Annual Review; No CMS Updates. Minor revisions only.

Revision Date: 12/18/2019: Annual Review; CMS Updated Coverage for E0766, Removed the following "**Tumor Transmitting Fields (TTF)** The Novo TTF -100A is a portable, wearable, battery operated device recently approved by the FDA to use in the treatment of recurrent Glioblastoma. The TTF uses electrical fields within the human body that are inferred to disrupt the rapid cell division exhibited by cancer cells. The FDA approved the device to use with adults with histologically confirmed glioblastoma multiforme (GBM) with recurrence in the supra-tentorial region of the brain after receiving chemotherapy. This device is used as a mono-therapy and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. Per CGS local coverage determination; tumor field treatment therapy (E0766, A4555) is not reasonable and necessary and is not covered, effective 08/01/2014." from the When Coverage will not be Approved.

Revision Date: 12/15/21; Annual Review; No CMS Updates, Minor Revisions Only.

Approval Dates:

Medical Coverage Policy Committee: December 15, 2021

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Medical Policy Coordinator