



Medicare Part C Medical Coverage Policy

Sacral Nerve Stimulators for Urinary Incontinence and Fecal Incontinence

Origination: June 30, 1988
Review Date: March 17, 2021
Next Review: March, 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

Sacral nerve stimulation (SNS) is a pulse generator device that transmits electrical impulses to the sacral nerve through an implanted wire. SNS is the implantation of a permanent device that stimulates the sacral nerves and helps to control bladder function and fecal incontinence in members who have failed behavioral and/or pharmacologic therapies. SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates.

POLICY STATEMENT

Coverage will be provided for SNS 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 (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and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

1) **Preauthorization by the Plan is required.**

2) SNS is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome and urinary retention. Both the test and the permanent implantation may be considered medically necessary when **all of the following criteria** are met:

a) The member's urinary condition is refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and the member is an appropriate surgical candidate such that implantation with anesthesia can occur.

AND

b) The member does not have stress incontinence, urinary obstruction, or specific neurologic disease (e.g., diabetes with peripheral nerve involvement) that is associated with secondary manifestations of the above three indications.

AND

c) The member has had successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, (s) he must demonstrate a fifty percent (50%) or greater improvement through test stimulation. Improvement is measured through voiding diaries.

1. SNS treatment involves two steps:

a. Test Stimulation; **AND**

b. Implantation.

The test stimulation may be performed percutaneously (CPT 64561). Also acceptable is a staged approach during which placement of the electrodes is done by incision (CPT 64581). If the trial is successful, the implantation of the stimulator follows (CPT 64590). During the course of this staged implant, CPT 64581 may be billed only once, unless there are extraordinary clinical circumstances requiring replacement of the leads. The medical necessity for the latter must be documented in the medical record.

Patients who achieve at least a fifty percent (50%) reduction in their symptoms during the three (3) to five (5)-day test stimulation period are considered appropriate candidates for implantation.

AND

d) The member is able to demonstrate an adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

3. Coverage for Sacral Stimulation for Fecal Incontinence

- Complete medical evaluation to rule out treatable diseases (Diagnosis , prior treatment etc)
- Chronic Fecal Incontinence of greater than two (2) incontinent episodes on average per week with duration greater than six (6) months.
- Evidence of unsuccessful conservative therapy as dietary modification, bulking and pharmacological treatment.
- Evidence that neuromodulation treatments successfully improve incontinence via a percutaneous test stimulation period which demonstrates at least fifty percent (50%) improvement in symptoms.

WHEN COVERAGE WILL NOT BE APPROVED

SNS for Urinary Incontinence and Fecal Incontinence is considered not medically necessary if:

All the coverage criteria are not met.

1. Sacral Nerve Stimulation for Fecal Incontinence is contraindicated if the following apply:
 - If the condition is related to anorectal malformation or defects of the anal sphincter over sixty (60) degrees, visible sequelae of pelvic radiation as active anal abscesses or fistula, or chronic inflammatory bowel disease
 - Incontinence is related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.
 - Sacral nerve neuromodulation is considered experimental, investigational and unproven in the treatment of chronic constipation or chronic pelvic pain.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: 64561, 64581, 64585, 64590, 64595, 95970, 95971, 95972, 95973, A4290, E0745, L8679, L8681, L8682, L8683, L8684, 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 Sacral Nerve Stimulation for Urinary Incontinence, (ID #230.18), Effective date, 01/01/2002, Accessed via Internet site www.cms.gov; viewed on 3/2/21.

2. BCBS Corporate Medical Policy on Sacral Nerve Neuromodulation/Stimulation of Pelvic Floor Dysfunction, Effective 11/11/2014, accessed via the Internet www.bcbsnc.com on, 3/20/19.
3. J11 Part B Medicare Advisory; 2014 update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies Fee Schedule; February Issue; Volume 2014; Issue 1.
4. Medicare National Coverage Determination Manual – 230.18 Sacral Nerve stimulation for Urinary Incontinence (Rev. 1, 10/03/2003, Accessed via http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part4.pdf on 3/20/2019.

Policy Implementation/Update Information:

Revision Dates: April 24, 2000; November 3, 2003 (Policy renamed: Sacral Nerve Stimulators for Urinary Incontinence, 11/3/2003. Previous policy name: Electrical Stimulators – Bladder); June 22, 2005

Revision Date: February 21, 2007: Updated codes; no criteria changes made May 16, 2007: Removed one-year history of urinary symptoms from criteria due to change in CMS policy.

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Revision Date: September 2009: Re-worded “When coverage will be approved section” to mirror Medicare language; Formatting changes.

Revision Date: February 20, 2013; Annual review, No changes to criteria for Urinary Incontinence; Added criteria for Fecal Incontinence as well as when coverage for fecal incontinence is not covered.

Revision Date: February 19, 2014; updated codes; Deleted L8685; L8686; L8687; L9688 and added L8679.

Revision Date: April 6, 2015: updated references with current Novitas LCD L34707 removed retired LCD and related Article references; removed code L8680 as it was removed from CMS coverage as of 4/1/14. October 29, 2015 removed LCD reference due to ICD-10 update only; no current local coverage determination.

Revision Date: March 15, 2017: No updates to coverage criteria. No revisions to policy.

Revision Date: March 20, 2019; Annual Review; No CMS updates. Minor Revisions Only.

Revision Date: March 17, 2021; Annual Review; No CMS updates. Minor Revisions Only.

Approval Dates:

Medical Coverage Policy Committee: March 17, 2021

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