

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: MP.110.MH
Last Review Date: 08/09/2018
Effective Date: 10/01/2018

MP.110.MH – Sacral Nerve Stimulators

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Sacral Nerve Stimulators (SNS)** medically necessary for the following indications:

Urinary Incontinence

1. SNS is considered medically necessary for the treatment of any of the following conditions:
 - Urinary urge incontinence
 - Urgency-frequency syndrome
 - Urinary retentionAnd
2. When all of the following criteria are met:
 - The member must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
 - The member completed successful test/trial stimulation (The indications for a test/trial stimulator are the same as for permanent implantation)
 - The member demonstrates adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated

Note: Before a member is eligible for permanent implantation, they must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.

Fecal Incontinence

SNS is considered medically necessary for the treatment of **fecal incontinence** when all of the following are met:

- The member has chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than six months OR ≥ 12 months post vaginal childbirth

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- Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking agents and pharmacologic treatment)
- The member is an appropriate candidate for surgery with anesthesia
- The member had completed successful test/trial stimulation. (The indications for a test/trial stimulator are the same as for permanent implantation).

Note: Before a member is eligible for permanent implantation, they must demonstrate a 50% or greater improvement through test/trial stimulation over a two week period.

Limitations

SNS is considered not medically necessary and is therefore not covered for the following:

1. Urinary Incontinence – members with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications are excluded.
2. Fecal Incontinence:
 - Conditions related to an anorectal malformation: congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae
 - Chronic inflammatory bowel disease (IBD)
 - Damage to tissue due to pelvic radiation
 - Sacral nerve neuromodulation is considered experimental, investigational and unproven in the treatment of chronic constipation or chronic pelvic pain

Background

Sacral nerve stimulation (SNS) is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder function. SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. This treatment involves electrical stimulation of the sacral nerves in the lower region of the spine via a totally implantable system. System components include a lead, an implantable pulse generator and an extension that connects the lead to the pulse generator. SNS is used for the treatment of urinary urge incontinence, urgency-frequency syndrome and urinary retention.

Codes:

| CPT Codes / HCPCS Codes / ICD-10 Codes | |
|--|-------------|
| Code | Description |

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| 64561 | Percutaneous implantation of neurostimulator electrodes, sacral nerve |
| 64581 | Insertion for implantation of neurostimulator electrodes, sacral nerve |
| A4290 | Sacral nerve stimulation test lead, each |
| ICD-10 codes covered if selection criteria are met: | |
| N31.8 | Other neuromuscular dysfunction of bladder |
| N36.44 | Muscular disorders of urethra |
| N39.41 | Urge incontinence |
| N39.46 | Mixed incontinence |
| R15.9 | Full incontinence of feces |
| R32 | Unspecified urinary incontinence |
| R33.8 | Other retention of urine |
| R33.9 | Retention of urine, unspecified |
| R35.0 | Frequency of micturition |
| R39.11 | Hesitancy of micturition |
| R39.14 | Feeling of incomplete bladder emptying |
| R39.81 | Functional urinary incontinence |
| R39.89 | Other symptoms and signs involving the genitourinary system |

References

1. Center for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 230.18 - Sacral Nerve Stimulation for Urinary Incontinence. Effective Date: 01/01/2002. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&bc=AgAAgAAAAAAAAAAA%3d%3d&>
2. Center for Medicare and Medicaid Services (CMS). Proposed/Draft Local Coverage Determination (LCD) No. L35449 - Sacral Nerve Stimulation (Contractor: Novitas Solutions, Inc.) Effective date 09/14/2017. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35449&ver=21&Date=&DocID=L35449&bc=iAAAABAAAAA&>
3. Hayes Medical Technology Directory. Implantable Sacral Nerve Stimulation for Urinary Voiding Dysfunction. Annual Review May 22, 2014.
4. National Institute for Health and Clinical Excellence (NICE). Interventional Procedure Guidance. IPG 99 - Sacral nerve stimulation for faecal incontinence. Issued November 2004.

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<https://www.nice.org.uk/guidance/ipg99/resources/guidance-sacral-nerve-stimulation-for-faecal-incontinence-pdf>

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