

Subject: Sacral Nerve Stimulation for Urinary and Fecal Incontinence

Medical Policy: 51.0 Original Effective Date: 11-17-2021
Status: Reviewed Last Review Date: 12/13/2023

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim, InterStim II, InterStim Micro) is a procedure which involves the implantation of electrodes:

- near the sacral nerve, which controls the function of the muscles required for urination
- at the sacral nerve to improve muscle control of the anal sphincter and improve rectal sensation.

Any condition outside these conditions mentioned in Gastric Electric Stimulation for the Treatment of Chronic Gastroparesis MPM 7.2 and/or Sacral Nerve Stimulation for Urinary and Fecal Incontinence MPM 51.0 will be reviewed on case-by-case basis by a Medical Director.

Coverage Determination

Prior Authorization is required for CPT code (64590 and 64595). Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

Coverage is for Medicare, Medicaid and Commercial.

1. Sacral Nerve Stimulation for Fecal Incontinence:

PHP will cover sacral nerve modulation/stimulation for fecal incontinence when all of the following criteria are met:

- Chronic fecal incontinence with greater than two incontinent episodes on average per week and duration of
 incontinence greater than six months or for more than twelve months after vaginal childbirth; AND
- Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); **AND**
- Upon a successful percutaneous (temporary) test stimulation, the member may proceed to permanent neurostimulator electrode. must meet
 - o defined as at least 50% sustained (more than one week) improvement in symptoms; AND
- Condition is not related to anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) and/or chronic inflammatory bowel disease; AND
- Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Sacral nerve modulation/stimulation is considered **experimental**, **investigational** and **unproven** for the treatment of chronic constipation or chronic pelvic pain.

2. Sacral Nerve Stimulation for Urinary Incontinence:

PHP follows NCD 230.18 Sacral Nerve Stimulation For Urinary Incontinence, for Medicare, Medicaid and Commercial. Direct stimulation of the sacral nerve(s) via an electrode array implanted at the level of the sacrum is the only treatment modality covered by the NCD.

Indications and Limitations of Coverage

Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation (CPT 64561) to determine if an implantable stimulator would be effective and a permanent implantation (CPT 64581) in appropriate candidates. Both the test and the permanent implantation are covered.

The following limitations for coverage apply to all three indications:

- Patient 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.
- Patients 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.
- Patient 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.

Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT code	Code Description for Sacral Nerve Stimulation for Fecal and Urinary Incontinence
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve including image guidance, if performed (Code 64561 should be reported when temporary or permanent leads are placed percutaneously)
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (Code 64581 should be reported when temporary or permanent leads are placed using an open approach)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter 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 by physician or other qualified health care professional; with simple spinal cord or peripheral nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with complex spinal cord or peripheral nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), non-hyphenrechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Neurostimulator lead test kit (implantable)
L8680	Implantable neurostimulator electrode, each

ICD-10-CM	Description:
N30.10	Interstitial cystitis (chronic) without hematuria
N30.11	Interstitial cystitis (chronic) with hematuria
N36.44	Muscular disorders of urethra
N39.41	Urge incontinence
N39.42	Incontinence without sensory awareness
N39.46	Mixed incontinence
N39.490	Overflow incontinence
N39.492	Postural (urinary) incontinence
N39.498	Other specified urinary incontinence

ICD-10-CM	Description:
R15.9	Full incontinence of feces
R32	Unspecified urinary incontinence
R33.0	Drug induced retention of urine
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
R39.15	Urgency of urination
R39.191	Need to immediately re-void
R39.192	Position dependent micturition

For Medicare listed diagnosis for Sacral Nerve Stimulation for Urinary Incontinence, see the following file: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR11655.zip

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Gray Clarke MD

Medical Director: Ana Maria Rael MD

Date Approved: 12/13/2023

References

- CMS, National Coverage Determination (NCD) 230.18, Sacral Nerve Stimulation For Urinary Incontinence, Version Number 1, Effective Date: 01/01/2022. [Cited 10/25/2023]
- CMS Manual System, Pub 100-20-One-Time Notification, Transmittal 10193, Change Request <u>11655</u>, Date: June 19, 2020. [Cited 10/23/2023]
- 3. CMS Manual System, Pub 100-20-One-Time Notification, Transmittal 2202, Change Request 11005, Date: Nov 9, 2018. [Cited 10/23/2023]
- 4. CMS, Noridian Healthcare Solution, Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017), Revision Date: 01/01/2020, R7. [Cited 10/25/2023]
- 5. CMS, CGS Administrators, LLC, Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A55835), Revision Date: 03/02/2023/R5. [Cited 10/13/2022]
- 6. CMS, Noridian Healthcare Solution, Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53359), Revision Date: 01/01/2020, R6. [Cited 10/25/2023]
- 7. CMS, Noridian, Peripheral Nerve Stimulation, LCA (A55530), revision date: 10/01/2023, R4. [Cited 10/25/2023]

Publication History

11-17-21 Original effective date. Reviewed by PHP Medical Policy Committee on 10/29/2021. New policy created specifically for urinary and fecal incontinence. The out of jurisdiction LCA (A53017) was used to help developed the fecal incontinence for all product line; and for urinary incontinence PHP will follow NCD (280.18) criteria for all product line. Codes (A4290, C1767, C1778, C1820, C1883 and C1897) are considered bundle to procedure per Status -N-per OPPS: Codes (C1883, C1897 and L8680) will be configured as Status N for all product line (these codes also apply to MPM 7.2 & MPM 22.4). For urinary and fecal incontinence, only those ICD-10 listed in "Group 1" in LCA (A53017) will be considered medically necessary for all product line.

CPT codes (64590 and 64595) will continue to require Prior Authorization for both MPM 51.0 and MPM 7.2. For all product lines, CPT codes (64590 and 64595) will be set to only pay when submitted with those diagnoses codes listed in "Group one" in both LCA (**A53017**-Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence) and LCA (**A55530** -Billing and Coding: Peripheral Nerve Stimulation); in addition to these listed codes from both LCAs, diagnoses code (K31.84) will also be included.

11-16-22 Annual review. Reviewed by PHP Medical Policy Committee on 10/14/2022. No change. For all LOBs fecal incontinence criteria remain unchanged. The urinary incontinence will continue to follow NCD (230.18) for all LOBs. Added language regarding any condition outside these conditions mentioned in MPM 7.2 and/or MPM 51.0 will be reviewed on case-by-case basis by a Medical Director. Format change: Combined duplicate CPT/HCPCS and ICD-10 codes. HCPCS codes (C1767, C1778, C1820, C1883, C1897) are still considered Status N-per OPPS Addendum B (Oct 2022). Continue configuration set in 2021 (for 64590 and 64595) since LCA (A55530) for Peripheral Nerve Stimulation and LCA (A53017) for Urine/Fecal incontinence plus ICD-10 code (K31.84) remains unchanged.

12-13-23 Annual review. Reviewed by PHP Medical Policy Committee on 10/25/2023. No change. For all LOBs fecal incontinence criteria remain unchanged. The urinary incontinence will continue to follow NCD (230.18) for all LOBs. Continue configuration set in 2021 for (64590 and 64595) using LCA (A55530) for Peripheral Nerve Stimulation and LCA (A53017) for Urine/Fecal incontinence plus ICD-10 code (K31.84). The update of configuration has been requested in the Gastroparesis MPM 7.2 regarding the revision to add ICD-10 (G43.E11 and G43.E19) per Noridian, LCA (A55530). No update to LCA (A53017).

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: Click here for Medical Policies

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.