PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 03/05/24
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 03/05/24
Clinical Policy Document: Neurostimulation, Sacral Nerve	**Replaces Effective Clinical Policy Dated:** 03/07/23
Reference #: MC/I008	**Page:** 1 of 5

PURPOSE:
The intent of this clinical policy is to ensure that services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage (COC), the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. For coverage to be considered, health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested.

GUIDELINES:
Medical Necessity Criteria – Requests for unilateral sacral nerve stimulation (SNS) - Must satisfy any of the following: I - III

I. *Overactive bladder (OAB)* (includes urinary *urge incontinence [UI]*, *urgency or frequency [UU, UF])*, or *non-obstructive urinary retention (NOUT)* – Must satisfy all of the following: A - C. If the request is for a trial stimulation of the device - must satisfy the following: A - B

   A. Symptoms lasting for greater than or equal to 12 months that have resulted in significant impairment in activities of daily living; and

   B. Conservative forms of treatment have been tried for at least 12 months – must satisfy one of the following: 1 or 2
      1. For o*veractive bladder* – both of the following: a and b
         a. Pharmacotherapy - at least 2 different antimuscarinic medications or a combination of an antimuscarinic (eg, Enablex [darifenacin], Sanctura [trospium], Toviaz [fesiteridine]) and a beta-adrenergic agonist (eg, Myrbetriq [mirabregon] Gemtesa [vibregron]); and
         b. Behavioral therapies (such as, but not limited to bladder training, bladder control strategies, pelvic floor muscle training, fluid management).

      2. For *non-obstructive urinary retention* – both of the following: a and b
         a. Pharmacotherapy - alpha blockers and cholinergic medications, and/or antibiotics for urinary tract infections; and
         b. Intermittent catheterization that has failed or is not well tolerated.

   C. Positive response to a temporary sacral nerve stimulator as shown by a greater than or equal to 50% reduction of symptoms.

II. *Fecal incontinence* – must satisfy all of the following: A - D. If the request is for a trial stimulation of the device - must satisfy all of the following: A - C

   A. Either of the following: 1 or 2
      1. Greater than 2 incontinent episodes per week, lasting for greater than 6 months; or
      2. Greater than 2 incontinent episodes per week, lasting for more than 12 months if SNS is requested following a vaginal birth.

B. Symptoms are not related to a medical (such as, but not limited to, spina bifida, pilonidal sinus, rectal prolapse) or surgical condition (such as, but not limited to, recent rectal surgery); and

C. Conservative forms of treatment have been tried (such as, but not limited to, pharmacotherapy, bowel training, diet modification, biofeedback, or pelvic floor exercise therapy); and

D. Positive response to a temporary sacral nerve stimulator as evidenced by a greater than or equal to 50% reduction of *fecal incontinence* symptoms.

III. Replacement or revision of stimulator generator/ battery, lead or electrode, or patient programmer - must satisfy the following: A, and B or C, as applicable

A. The indication for initial placement was for one of the following: 1 or 2
   1. Urinary *OAB* or *non-obstructive urinary retention*; or

   2. *Fecal incontinence.*

B. Request is for replacement of the existing generator/battery or patient programmer - must satisfy one of the following: 1 - 2
   1. The battery life is less than 1 year; or

   2. The device is *malfunctioning* and no longer under warranty.

C. Request is for replacement and/or revision of lead/electrode due to migration and/or no longer functioning properly is considered medically necessary.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

The following are considered investigative (see Investigative List): I - III

I. Chronic constipation

II. Chronic pelvic pain

III. Stress incontinence (does not include mixed incontinence)

DEFINITIONS:
Fecal incontinence:
Can be caused by various mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems (CNS/PNS), and voluntary and involuntary muscles; more common in women due to muscular and neural damage during vaginal child delivery.

Malfunctioning:
The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

Non-obstructive urinary retention:
Inability to empty the urinary bladder completely.

Overactive bladder:
The presence of "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI), in the absence of UTI or other obvious pathology."4 Therefore, OAB symptoms consist of four components: urgency, frequency, nocturia and urgency incontinence. OAB studies have used varying combinations of these symptoms to identify patients for study inclusion and to define treatment response.

Sacral nerve stimulation (SNS):
Implanted electrodes at the sacral nerve site that control the muscles required for bladder and rectal functioning.

Urge incontinence:
Urine leakage when there is a strong urge to void

Urgency or frequency:
Uncontrollable urge to urinate frequently and in small volumes.

BACKGROUND:
Sacral nerve stimulation (SNS) is also known as sacral nerve neuromodulation. It delivers low-voltage electrical current to specific sacral nerve/s that lead to pelvic floor muscles and/or pelvic organs. There are two phases to SNS: temporary and permanent implantation. The temporary phase involves percutaneously introducing a temporary electrode into the left or right sacral nerve foramen. An external device then provides continuous stimulation. The length of the temporary phase varies, although it usually lasts for a week.

If the temporary phase shows evidence that SNS is effective (greater than or equal to 50% reduction in symptoms), a permanent SNS device is then implanted. The temporary electrodes are replaced by permanent ones which are then also connected to sacral nerves (usually the S3 nerve root) and an implantable pulse generator is surgically positioned in the upper buttock region. After implantation, the physician adjusts the pulse generator to its optimal settings for the patient by using a programming console. A control magnet to turn the pulse generator on or off by placing it over the pulse generator area for 1-2 seconds is then given to the patient.

Examples of devices are InterStim Continence Control Therapy, InterStim Micro System, and Axonics.

Prior Authorization: Yes, per network provider agreement.

CODING:

CPT® , HCPCS

64561 Percutaneous implantation of neurostimulator electrode array; sacral nerve, (transforaminal placement), including image guidance if performed [used for trial/temporary placement]

64581 Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. Clemens JQ. Urinary incontinence in men. (Topic 14611, Version 49.0; last updated: 01/03/2022. In: Givens J, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2022. www.uptodate.com. Accessed 11-04-22.
4. Gie O, & Christoforidis D. Advances in the treatment of fecal incontinence. 2011. *Semin Colon Rectal Surg*, 22:30-38.
5. Clemens JQ. Interstitial cystitis/bladder pain syndrome: Management. (Topic 8087, Version 52.0; last updated: 12/12/23). In: Givens J, Eckler K, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2022. www.uptodate.com. Accessed 12-26-23.
6. Lukacz ES. Urgency urinary incontinence/overactive bladder (OAB) in females: Treatment. (Topic 114501, Version 33.0; last updated: 12/01/23). In: Givens J, Eckler K, eds. *UpToDate*. Waltham, Mass.: UpToDate; 2022. www.uptodate.com. Accessed 12-26-23.
7. Lukacz ES. Female urinary incontinence, Treatment (Topic 6881, Version 96.0; last updated: 05/25/23). In: Givens J, Eckler K, eds. *UpToDate*. Waltham, Mass.: UpToDate; 2022. www.uptodate.com. Accessed 12/01/23.
8. US Food and Drug Admin. Code of Federal Regulations Title 21, Volume 8, Subpart A, Sec 803.3, (k) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803&showFR=1 Accessed on 12-26-23.
9. Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults: an AUA/SUFU Guideline. American Urological Association. AUA/SUFU Guideline: Published 2012; Amended 2014, 2019. Retrieved from: https://www.auanet.org/guidelines-and-quality/guidelines/non-oncology-guidelines Accessed 12-26-23.
10. National Institute for Clinical Excellence (NICE). Sacral nerve stimulation for idiopathic chronic nonobstructive urinary retention. November 2015. Retrieved from: https://www.nice.org.uk/guidance/ipg536. Accessed 12-26-23.

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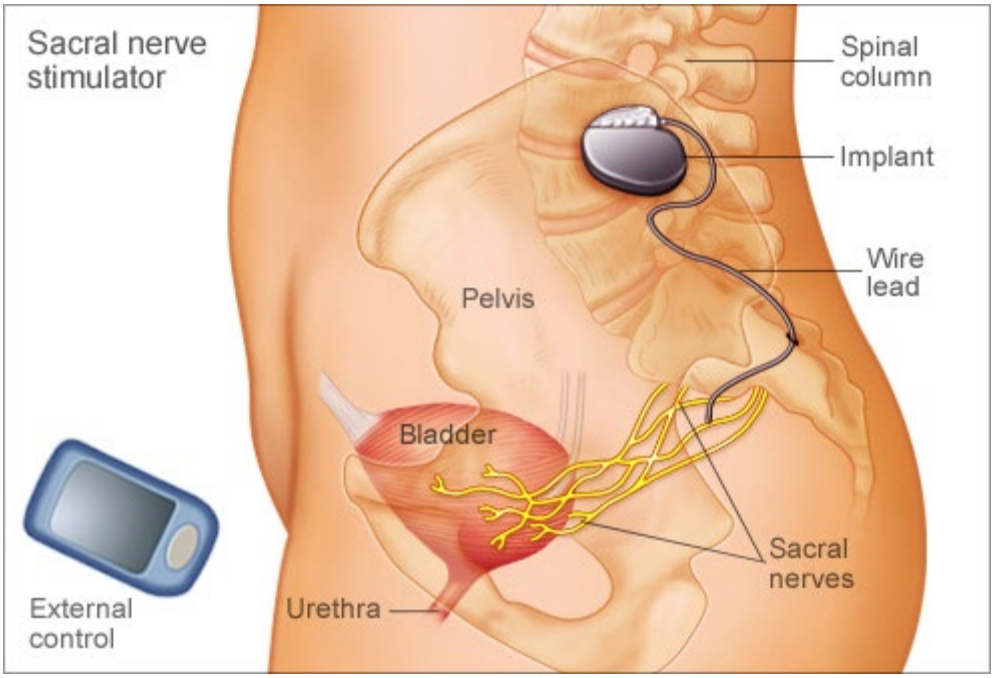
Attachment A

Image of Implanted Sacral Nerve Stimulator
Retrieved from WebMD



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- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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- Information written in other languages

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Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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