# BENEFIT COVERAGE POLICY

**Title:** BCP-81 Sacral Nerve Stimulation for Urinary and Fecal Incontinence

Effective Date: 7/1/2023

Physicians Health Plan
PHP Insurance Company
PHP Service Company

**Important Information - Please Read Before Using This Policy**

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

**1.0 Policy:**

Health Plan considers sacral nerve stimulation/neuromodulation as medically necessary for the management of members with urinary voiding dysfunction and fecal incontinence and who meet the criteria listed below in the Clinical Determination Guidelines.

Services for sacral nerve stimulation/neuromodulation require authorization/approval prior to the health service being provided.

For all non-network covered services to be paid at the network benefit level except for emergency/urgent services, prior approval is required.

Refer to the member's benefit coverage document for specific benefit description, guidelines, coverage, and exclusions.

**2.0 Background:**

Sacral nerve neuromodulation (SNM), also known as sacral nerve stimulation (SNS), is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. SNM is a safe, effective, and minimally invasive advanced therapy indicated to treat urinary incontinence, urinary retention, urgency, frequency, and fecal incontinence for patient refractory to behavioral and pharmacologic treatment.

Sacral neuromodulation therapy was developed in 1982 by Tanagho and Schmidy, gaining FDA approval in 1997. To date, there have been more than 300,000 patients treated with sacral neuromodulation implants worldwide. Reviewers suggest that between 16% to 29% of the population, with a few estimating up to 75% experience some level of overactive bladder, including symptoms of urinary incontinence, urgency, or frequency. Additionally, an estimated 25% to 40% of patients experiencing overactive bladder fail to achieve satisfactory results after first and second-line therapy. These patients have a refractory overactive bladder and may be eligible for SNM therapy. (Feloney, Stauss, Leslie, 2022)

The exact mechanism of action is unclear. Sacral nerve stimulation applies a low amplitude electrical current to a sacral nerve through an electrode that is placed through a corresponding sacral foramen. The stimulation of the sacral nerves leads to recruitment of the pelvic floor musculature and pelvic organs, leading to improvement in pelvic floor function. The third sacral foramen is the level at which an optimal response is most commonly elicited. The third sacral nerve root contains afferent sensory

and efferent autonomic motor nerves and voluntary somatic fibers, which may, alone or in harmony, create the beneficial effect elicited by SNS.

This policy addresses use of SNM in the treatment of urinary or fecal incontinence, urinary or fecal nonobstructive retention and chronic pelvic pain in patients with intact neural innervation of the bladder and/or rectum.

Urinary Incontinence:

Urgency-Frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes and is prominent symptom of interstitial cystitis. Urinary retention is the ability to completely empty the bladder of urine.

Fecal Incontinence:

Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

**3.0 Clinical Determination Guidelines:**

A. Urinary Incontinence and Non-obstructive Retention:

1. Trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead is proven and medically necessary for treating urinary voiding dysfunction when **all** the following criteria are met:
    a. Diagnosis of at least one of the following:
        i. Urge incontinence
        ii. Urgency-frequency syndrome
        iii. Non-obstructive urinary retention
        iv. Overactive bladder symptoms
    b. Bladder capacity of 100ml or greater
    c. Urinary voiding dysfunction is not secondary to neurologic disease/condition origin
    d. No bladder outlet obstruction
    e. Documented failure or intolerance to conservative therapies (e.g., bladder training, pelvic floor rehabilitation, pharmacological therapy)
    f. Individual capable of operating sacral nerve stimulating device.
2. Permanent implantation of a sacral nerve neuromodulation device is established in patients who meet **all** the following criteria:
    a. All the criteria for sacral nerve stimulation for urinary incontinence screening trial have been met see 1. a-f.
    b. Improvement in reported symptoms of 50% of greater in response to screening trial of sacral nerve stimulation.
3. Sacral nerve stimulator replacement or revision is considered medically necessary when the individual has met all the above criteria and the existing device cannot be repaired or is no longer under warranty.
4. Removal of sacral nerve stimulator and all related components is proven and medically necessary.

5. Exclusions
    a. Other urinary/voiding applications of sacral nerve neuromodulation are considered experimental/investigational, including but not limited to treatment of:
        i. Urinary voiding dysfunction due to neurologic condition, (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury or other types of chronic voiding dysfunction)

B. Fecal Incontinence:

1. Sacral nerve neuromodulation screening trial is proven and medically necessary for treatment of Fecal Incontinence when **all** the following criteria are met:
    a. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered established in patients who meet **all** the following criteria:
        i. There is a diagnosis of chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than six months, or for more than twelve months after vaginal childbirth.
        ii. Symptoms refractory to conservative care (e.g., bowel training, bulking agents, pelvic floor rehabilitation)
        iii. The patient is an appropriate surgical candidate.
        iv. The condition is not related to an 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) or chronic inflammatory bowel disease.
        v. Fecal Incontinence is not secondary to a neurologic disease/condition origin
        vi. Fecal Incontinence is not secondary to Constipation
        vii. The patient has not had rectal surgery in the past 24 hours.
        viii. Individual capable of operating sacral nerve stimulating device
    b. Permanent implantation of a sacral nerve neuromodulation device may be considered established in patients who meet all the following criteria:
        i. All the criteria for sacral nerve stimulation for fecal incontinence screening trial have been met in 1. A. i.-viii.
        ii. Improvement in reported symptoms of 50% of greater in response to screening trial of sacral nerve stimulation.
    c. Exclusions:
        i. Sacral nerve neuromodulation is considered experimental/investigational for the treatment of chronic constipation or chronic pelvic pain.

**4.0 Coding:**

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = EPO/PPO; 3 = ASO Group L0000264; 4 = ASO Group L0001269 Non-Union & Union; 5 = ASO Group L0001631; 6

= ASO Group L0002011; 7 = ASO Group L000269 Union Only; 8 = ASO group L0002184; 9 = ASO group L0002237; 10 = ASO group L0002193.

| COVERED CODES | | | |
|---|---|---|---|
| **Code** | **Description** | **Prior Approval** | **COC Reference** |
| 64561 | Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed | Y | Professional Fees for Medical or Surgical Services |
| 64581 | Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) | Y | Professional Fees for Medical or Surgical Services |
| 64585 | Revision or removal of peripheral neurostimulator electrode array | N | Professional Fees for Medical or Surgical Services |
| 64590 | Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling | Y | Professional Fees for Medical or Surgical Services |
| 64595 | Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver | N | Professional Fees for Medical or Surgical Services |
| 95970 | Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) 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 | N | Professional Fees for Medical or Surgical Services |
| 95971 | Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional | N | Professional Fees for Medical or Surgical Services |
| 95972 | Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose | N | Professional Fees for Medical or Surgical Services |

| COVERED CODES | | | |
|---|---|---|---|
| **Code** | **Description** | **Prior Approval** | **COC Reference** |
| | lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional | | |
| A4290 | Sacral nerve stimulation test lead, each | Y | Durable Medical Equipment (DME) |
| E0745 | Neuromuscular stimulator, electronic shock unit | Y | Durable Medical Equipment (DME) |
| E1399 | Durable medical equipment, miscellaneous | Y | Durable Medical Equipment (DME) |
| L8679 | Implantable neurostimulator, pulse generator, any type | Y | Prosthetic Devices |
| L8680 | Implantable neurostimulator electrode, each | Y | Prosthetic Devices |
| L8682 | Implantable neurostimulator radiofrequency receiver | Y | Prosthetic Devices |
| L8685 | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension | Y | Prosthetic Devices |
| L8686 | Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension | Y | Prosthetic Devices |
| L8687 | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension | Y | Prosthetic Devices |
| L8688 | Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension | Y | Prosthetic Devices |

**5.0 Unique Configuration/Prior Approval/Coverage Details:**

None.

**6.0 Terms & Definitions**:

Urinary Incontinence: Urge Incontinence is a type of Urinary Incontinence in adults, which involves sudden compelling urges to void and results in involuntary leakage of urine.

Stress Incontinence: Occurs when urine leaks as pressure is put on the bladder, such as during exercise, coughing, sneezing, laughing, or lifting heavy objects.

Urge Incontinence: happen when people have a sudden need to urinate and cannot hold their urine long enough to get to the toilet.

Fecal Incontinence: is the inability to control bowel movements, causing stool (feces) to leak unexpectedly from rectum.

**7.0 References, Citations & Resources:**

Abello A, Das AK. Electrical neuromodulation in the management of lower urinary tract dysfunction: evidence, experience, and future prospects. Ther Adv Urol. 2018 Feb 22;10(5):165-173

"Fecal Incontinence." American College of Gastroenterology, https://gi.org/topics/fecal-incontinence/.

Feloney MP, Stauss K, Leslie SW. Sacral Neuromodulation. [Updated 2022 Nov 28]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK567751/

Mellgren A. Fecal incontinence. Surg Clin North Am. 2010 Feb;90(1):185-94, Table of Contents

"Urinary Incontinence in Older Adults." National Institute on Aging, U.S. Department of Health and Human Services, https://www.nia.nih.gov/health/urinary-incontinence-older-adults#:~:text=Urinary%20incontinence%20means%20a%20person,to%20avoid%20their%20normal%20activities

## 8.0 Associated Documents [For internal use only]:

Policies and Procedures (P&Ps) - MMP-09 Benefit Determinations MMP-02 Transition and Continuity of Care, UMPP-02 Peer to Peer Conversations

Standard Operating Procedure (SOP) - MMS-03 Algorithm for Use of Criteria for Benefit Determinations; MMS-52 Inpatient Case Process in CCA; MMS-53 Outpatient Case Process in CCA

Sample Letter – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Partial Coverage, Partial Non-Coverage Letter; Specific Exclusion Denial Letter, Lack of Information Letter

Form – Request Form: Out of Network/ Prior Authorization

## 9.0 Revision History

Original Effective Date: 03/06/2023

Next Review Date: 07/27/2024

| Revision Date | Reason for Revision |
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