MEDICAL POLICY

Medical Policy Title	**Sacral Nerve Stimulation**
Policy Number	**7.01.10**
Current Effective Date	June 26, 2025
Next Review Date	June 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Sacral Nerve Stimulation for the Treatment of Urinary Conditions

I. Sacral nerve stimulation is a **medically appropriate** treatment option for individuals ≥ 16 years who meet specific criteria for **BOTH** Trial Stimulation **AND** Permanent Placement:

   A. Trial Stimulation

      1. Demonstrated at least 50% improvement in voiding incontinence and urinary symptoms; **or**
      2. A 50% decrease in residual urine volume; **and**

   B. Permanent Placement

      1. Individual has a diagnosis of chronic, idiopathic, non-obstructive, urinary retention who meet the following criteria:
         a. failed clean-self-catheterization; **or**
         b. have not tolerated clean-self-catheterization; **or**
      2. Individual has a diagnosis of urgency-frequency syndrome, overactive bladder, or urge incontinence that is unrelated to a neurological condition, who meets the following criteria:
         a. symptoms have persisted for more than six (6) months; **and**
         b. documentation supports the following:
            i. failure of conventional treatments (e.g., pelvic floor exercises, lifestyle therapy, bladder training); **and**
            ii. failure of **ONE** of the following pharmacologic treatments:
               a) two (2) different anticholinergics; or
               b) one (1) anticholinergic and one (1) beta-3 adrenergic agonist.

II. Sacral nerve stimulation is considered **investigational** for **ALL** other indications, including, but not limited to, the following:

   A. Stress incontinence;

B. Urge incontinence due to a neurological condition (e.g., diabetic neuropathy, multiple sclerosis, spinal cord injury);

C. Other types of chronic voiding dysfunction.

Sacral Nerve Stimulation for the Treatment of Fecal Incontinence

III. Sacral nerve stimulation is a **medically appropriate** treatment option for individuals ≥ 16 years who have fecal incontinence, when **ALL** of the following indications are met:

A. Have demonstrated an appropriate response to trial stimulation. An appropriate response is defined as at least a 50% improvement in voiding/incontinence for fecal symptoms;

B. Chronic fecal incontinence of greater than two (2) episodes per week with a duration greater than six (6) months (or 12 months, if occurring after vaginal childbirth);

C. Documented failure of prescribed conservative therapies (e.g., pharmacologic treatments, dietary changes) performed for more than three (3) months; **and**

D. Incontinence unrelated to an anorectal malformation, chronic inflammatory bowel disease, or neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Device Repair

IV. Repair of a medically necessary sacral nerve stimulator or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. Date of device implantation/initiation;
2. Manufacturer warranty information, if applicable;
3. Attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:
1. Inadequate function interferes with activities of daily living; **and**
2. Repair is expected to make the equipment fully functional (as defined by manufacturer).

C. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is ineligible for coverage.

Device Replacement

V. Replacement of a medically necessary sacral nerve stimulator or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VI. The replacement of a properly functioning sacral nerve stimulator, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;

VII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

IX. Accessories or components for sacral nerve stimulators that are considered **not medically necessary or investigational** by peer-reviewed literature will also be considered as not medically necessary or investigational by the Health Plan.

X. Sacral nerve stimulation is considered **investigational** for **ALL** other indications, including, but not limited to, the following:

A. Stress incontinence;

B. Urge incontinence due to a neurological condition (e.g., diabetic neuropathy, multiple sclerosis, spinal cord injury);

C. Other types of chronic voiding dysfunction;

D. Constipation;

E. Chronic pelvic pain.

XI. Bilateral sacral nerve stimulation is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

7.01.66 Radiofrequency Treatment for Fecal Incontinence

8.01.22 Tibial Nerve Stimulation for Voiding Dysfunction

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Urinary voiding dysfunction is usually defined as the inability to control urination. Urinary voiding disorders are generally divided into five (5) types, depending on the pathophysiology involved: urge

incontinence (a subtype of which is urgency-frequency syndrome), overflow incontinence (also known as urinary retention), stress incontinence, mixed incontinence, and functional incontinence. Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes. Urgency-frequency is a prominent symptom of interstitial cystitis. The term "overactive" bladder is frequently used when describing the symptoms of urgency-frequency and urge incontinence. Urinary retention is the inability to completely empty the bladder of urine.

Fecal incontinence is defined as the uncontrolled passage of feces or gas for at least one month's duration, in an individual of at least four (4) years of age, who had previously achieved control (Paquette et al., 2015).

Sacral nerve stimulation (SNS), or sacral neuromodulation (SNM), is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. The SNS device consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet is kept by the patient and can be used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

Treatment using SNS is one of several alternative modalities for patients with urinary urge incontinence, significant symptoms of urgency-frequency, or non-obstructive urinary retention who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for four to seven days. This lead is connected to an external stimulator, which is carried in the patient's pocket or on the patient's belt. Patients who show a 50% or greater reduction in symptom frequency are deemed eligible for the permanent device. The second type of testing is a two-stage surgical procedure. In stage one, a quadripolar-tined lead is implanted and tested for as long as several weeks. Patients who show a 50% or greater reduction in symptom frequency can proceed to stage two of the surgery, which is the permanent implantation of the neuromodulation device. The two-stage surgical procedure has been used in various ways, including as an alternative to PNE, for patients who failed PNE, for patients with an inconclusive PNE, or to further refine patient selection for patients who had a successful PNE. Approximately 63% of patients have a successful testing phase. The permanent device is implanted under general anesthesia, with the pulse generator inserted in the upper gluteal region.

SNS has also been proposed as a treatment for chronic constipation and pelvic pain.

SUPPORTIVE LITERATURE

There is sufficient scientific evidence to conclude that SNS is safe and effective for the treatment of urgency-frequency and non-obstructive urinary retention that is not of neurogenic origin and that

health outcomes are improved. Good outcomes have been achieved outside of investigational settings. Overall clinical success rates, defined by at least a 50% reduction in voiding dysfunction symptoms, were 72%, 83%, and 88% for patients with urge incontinence, non-obstructive urinary retention, and urinary urgency-frequency, respectively. The benefits of SNS have been reported to be sustained for up to five (5) years in patients for whom there is long-term follow-up data available.

There are consistent and longer-term results from two large trials in 2010 (a prospective, multi-center, investigational trial with 120 patients and a European cohort of 177 patients) in support of SNS for the treatment of fecal incontinence. Together with a randomized, controlled trial with a 12-month follow-up from 2008, evidence is considered sufficient for SNS to be an option for the treatment of chronic fecal incontinence in well-selected patients who have failed conservative therapy. It should be emphasized that not all patients will benefit and that the adverse event rate for this procedure, including serious adverse events, is high. Patients should, therefore, be provided with adequate information to make an informed choice regarding the potential risks and benefits of this procedure.

There is insufficient published data to draw conclusions about the efficacy of SNS for patients with urinary urgency-frequency or retention of neurologic origin. Studies focusing on the use of SNS for constipation and pelvic pain consist mostly of small case series with follow-ups of short duration. The safety and efficacy of SNS for these newer indications have yet to be proven in well-designed clinical trials. Currently, these are not U.S. Food and Drug Administration (FDA) approved indications.

Bilateral SNS has been suggested as a consideration if treatment with unilateral SNS is ineffective; however, evidence at this time is insufficient.

PROFESSIONAL GUIDELINE(S)

The most recent update of the American College of Obstetricians and Gynecologists (ACOG) practice bulletin for Urinary Incontinence in Women (2015) suggests consideration of sacral neuromodulation for patients with recalcitrant urinary urge incontinence who have failed other conservative measures.

Bharucha and colleagues (2017) published an American Gastroenterological Association (AGA) clinical practice update expert review of best practices for the management of fecal incontinence using surgical interventions and device-aided therapy. They advised that SNS should be considered for patients with moderate-to-severe fecal incontinence in whom symptoms have not responded after a three-month or longer trial of conservative measures. In addition, the authors found no evidence that SNS improves bowel symptoms or rectal evacuation in defecatory disorders.

The 2019 American Urological Association guidelines on the diagnosis and treatment of overactive bladder states that sacral neuromodulation may be offered as a third-line treatment in carefully selected individuals with severe refractory symptoms or in those who are not candidates for second-line therapy (e.g., oral antimuscarinics, oral β3-adrenoceptor agonists, transdermal oxybutynin) and are willing to undergo surgery (recommendation, evidence strength Grade C), (Lightner et al., 2019).

In 2020, the National Institute for Health and Care excellence (NICE) issued guidance on the Axonics sacral neuromodulation system for treating refractory overactive bladder. The guidance states that the Axonics system should be considered an option for people with refractory overactive bladder.

Similar to the 2004 guidance it states that use of SNS for urge incontinence and symptoms of urgency or frequency is supported by evidence of efficacy and safety.

In 2016, the American Society of Colon and Rectal Surgeons (ASCRS) released a clinical practice guideline for the management of constipation. The guidelines states that sacral neuromodulation may be an effective treatment for individuals with chronic constipation and successful peripheral nerve evaluation test when conservative measures have failed. However, it is not currently approved by the U.S. FDA for this condition in the United States (Grade of Recommendation: Weak, based on moderate quality evidence, 2B).

In 2023, the ASCRS released an updated clinical practice guideline for the treatment of fecal incontinence. The guidelines state that sacral neuromodulation may be considered as a first-line surgical option for incontinent individuals with and without sphincter defects (strength of recommendation, conditional; GRADE quality of evidence is low).

REGULATORY STATUS

There are two SNS systems currently approved by the United States Food and Drug Administration (FDA) for use in the treatment of urge incontinence, urgency-frequency, non-obstructive urinary retention, and fecal incontinence. The Interstim Sacral Nerve Stimulation System from Medtronic received approval in 1997 for urge incontinence, in 1999 for urgency-frequency and nonobstructive urinary retention, and in 2011 for fecal incontinence. The Axonic Sacral Neuromodulation System from Axonics received FDA approval for the treatment of urge incontinence, urgency-frequency, and non-obstructive urinary retention, and received pre-market approval for fecal incontinence, in 2019.

Medtronic has since received FDA approval for different models of SNS devices, the Interstim Micro, a small rechargeable device with 15 years of battery life, and the Interstim X, a recharge-free device, offering more than 10 years of battery life without any need to recharge. Both devices utilize a programming device in the form of what looks like a smartphone so that patients can discreetly adjust their own settings. Both devices have magnetic resonance imaging (MRI) modes and allow for full body 1.5T and 3T MRI scans under certain conditions.

In 2023, the Virtis Sacral Neuromodulation System (Nuvectra) was approved by the FDA for treatment of urinary retention and symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency in individuals who have failed more conservative treatments. FDA product code: EZW. [Internet]. [accessed 2025 Mar 17]. Available from: Devices@FDA

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver.
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array.
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., 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).
95971	with simple spinal cord, or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter-programming by physician or other qualified health care professional
95972	with complex spinal cord, or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/ transmitter, programming by physician or other qualified health care professional
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed (effective 01/01/24).
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters

Code	Description
0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters

HCPCS Codes

Code	Description
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684	Radiofrequency transmitter (external) for use with implantable sacral root stimulator receiver for bowel and bladder management, replacement
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

Code	Description
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

ICD10 Codes

Code	Description
N32.81	Overactive bladder
N39.41	Urge incontinence
R15.0-R15.9	Fecal incontinence (code range)
R33.0-R33.9	Retention of urine (code range)
R35.0	Frequency of micturition
K59.00-K59.09	Constipation (code range)
R10.2	Pelvic and perineal pain
N39.3	Stress incontinence (male or female)
N39.42	Incontinence without sensory awareness

REFERENCES

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Sacral Nerve Stimulation for Urinary Incontinence (NCD 230.18) [accessed 2025 Mar 17]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
10/18/01, 06/20/02, 06/19/03, 05/19/04, 05/18/05, 03/16/06, 02/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18, 03/21/19, 02/20/20, 04/15/21, 04/21/22, 04/20/23, 06/20/24, 06/26/25	
Date	**Summary of Changes**
06/26/25	• Annual policy review; policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date