MEDICAL POLICY

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Medical Policy Title	**Sacral Nerve Stimulation**
Policy Number	**7.01.10**
Current Effective Date	**March 16, 2026**
Next Review Date	**November 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. Individual has a diagnosis of chronic, idiopathic, non-obstructive, urinary retention who meet **ANY** of 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 **ALL** of 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;

AND

B. Permanent Placement

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

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;

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**.

VIII. 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.

IX. 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.

X. 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

8.01.22 Tibial Nerve Stimulation for Voiding Dysfunction

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Urinary Incontinence

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.

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.

Fecal Incontinence

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. Severity may range from involuntary passage of flatus to complete loss of bowel control.

SUPPORTIVE LITERATURE

Urinary Incontinence

In 1999, the FDA approved clinical studies of the Medtronic InterStim System for sacral nerve

stimulation, allowing a large multicenter, randomized clinical trial to evaluate the safety and effectiveness of SNS for treating urinary urgency/frequency. Patients underwent test stimulation, and those showing ≥50% improvement were randomized into treatment or control groups. For urinary retention, 83% of treated patients achieved successful outcomes at six (6) months, with sustained improvements observed at 12 and 18 months. Similarly, patients with urgency/frequency symptoms experienced significant reductions in daily voids, increased voided volumes, and reduced urgency, with 88% achieving clinical success at six (6) months. Safety data from 581 patients and 219 implants revealed that most adverse events were resolved, with a surgical revision rate of 33.3%. The therapy demonstrated reversible effects and did not compromise urologic function. Overall, the InterStim System was found to be safe and effective for patients who had failed or could not tolerate conservative treatments.

A study by Groen et al (2011) provided the longest follow-up data on SNM for women with refractory idiopathic urge urinary incontinence. In this longitudinal series, 60 patients were followed for at least five years after receiving the therapy. Treatment success was defined as a minimum 50% reduction in daily incontinent episodes or pad usage. At one (1) month, 87% of patients met this criterion, but the success rate declined to 62% by the five-year mark. Complete continence was achieved by 25% of patients at one (1) month and 15% at five (5) years. Despite the decrease in efficacy over time, 80% of the women continued using the device at five (5) years. Adverse events were reported in 53% of patients most commonly related to hardware issues or discomfort, and 15 patients required a total of 23 reoperations. Most pain-related complications were managed conservatively.

Schwarztuch et al (2024) evaluated the feasibility, safety, and efficacy of SNM in patients with neurogenic lower urinary tract dysfunction (NLUTD) and/or fecal incontinence (FI), comparing outcomes to those with non-neurogenic conditions. Conducted as a retrospective single center study from 2017 to 2022, 67 patients underwent two-stage implantation of the InterStim II device. Of these patients, 16 had underlying neurologic conditions such as multiple sclerosis, spinal stenosis, or Parkinson's disease. Clinical success was defined as a ≥50% improvement in catheterizations or incontinence episodes. Results showed comparable success rates between the neurogenic (50%) and non-neurogenic (56.9%) groups, with no significant differences in surgical duration, follow-up, or device removal rates. Predictors of success included a maximal cystometric capacity below 430 mL and detrusor contraction during voiding. SNM was well tolerated in neurogenic patients, with low adverse event rates and no infections reported. Limitations of the study include a small sample size, heterogeneous patient characteristics, and a mid-term follow-up duration. Overall, the study supports SNM as a viable treatment option for carefully selected neurogenic patients who are refractory to conservative therapies, demonstrating similar outcomes to non-neurogenic populations.

Fecal Incontinence (FI)

Wexner et al (2010) evaluated the safety and effectiveness of SNS in a large patient population under an FDA approved investigational protocol for individuals with fecal incontinence. Patients who experienced a ≥50% improvement during the test stimulation phase received permanent implantation of the InterStim Therapy device (Medtronic, Minneapolis, MN). The primary efficacy endpoint was defined as achieving therapeutic success ≥50% reduction in weekly incontinent episodes at 12 months compared to baseline. Of the 133 patients who underwent test stimulation,

90% were successful. A total of 120 patients (110 female), with a mean age of 60.5 years and an average FI duration of 6.8 years, received permanent implants. The mean follow-up duration was 28 months (range: 2.2–69.5 months). At 12 months, 83% of subjects met the criteria for therapeutic success (95% CI: 74%–90%; P < 0.0001), with 41% achieving complete continence. At 24 months, the success rate increased to 85%. The average number of weekly incontinent episodes decreased from 9.4 at baseline to 1.9 at 12 months and 2.9 at 24 months. No unexpected adverse device effects were reported.

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.

Vollebregt et al (2024) conducted a randomized, double-blind, multicenter crossover trial to evaluate the clinical efficacy and underlying mechanisms of subsensory SNM in adults with chronic fecal incontinence (FI) who had failed conservative treatment. The study included two 16-week treatment periods (active SNM vs. sham stimulation), followed by a 26-week open-label phase, totaling 58 weeks. A mechanistic sub-study using magnetoencephalography (MEG) assessed brain-anorectum connectivity. Due to COVID-19 disruptions, 39 participants were randomized, with 16 completing the primary outcome assessment. The primary endpoint reduction in FI episodes per week, showed a non-significant improvement with SNM compared to sham (−0.7 episodes/week; p = 0.06). However, sensitivity analysis suggested a potentially meaningful effect (−0.9 episodes/week; p = 0.04). Open-label follow-up revealed sustained symptom improvement, with FI episodes decreasing from 6.2 to 3.2 per week, along with marked reductions in urgency and loperamide use. Mechanistic findings showed no significant differences in cortical responses between SNM and sham stimulation or between patients and healthy controls. MEG data confirmed bilateral sensorimotor activation during anal stimulation and voluntary squeeze, but SNM did not produce measurable changes in brain activity.

PROFESSIONAL GUIDELINE(S)

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.

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.

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

Medical Devices

The United States Food and Drug Administration (FDA) regulates medical devices including sacral nerve stimulators. All medical devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 17]

SNS has been approved by the Food and Drug Administration (FDA) since 1997 for the treatment of urinary urge incontinence, and its indications were later expanded to include urinary retention and urgency/frequency symptoms. 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.

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
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated

Code	Description
	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
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

Code	Description
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
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

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SEARCH TERMS

Sacral nerve stimulation (SNS) therapy, Sacral neuromodulation (SNM) for urinary incontinence, SNS treatment outcomes, SNS for fecal incontinence

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Sacral Nerve Stimulation for Urinary Incontinence (NCD 230.18) [accessed 2025 Oct 14]

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

11/19/99, 05/18/00, 08/16/01, 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, 11/20/25

Date	Summary of Changes
11/20/25	• Off cycle review to clarify sacral nerve stimulation trial and permanent placement criteria.
06/26/25	• Annual policy review; policy intent unchanged.

01/01/25	• Summary of changes tracking implemented.
11/19/99	• Original effective date