

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Sacral Nerve Stimulation
Policy Number	7.01.10
Category	Technology Assessment
Original Effective Date	11/19/99
Committee Approval Date	05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 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
Current Effective Date	04/20/23
Archive Date	N/A
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> <li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li> <li>• <i>If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</i></li> <li>• <i>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.</i></li> <li>• <i>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.</i></li> <li>• <i>If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</i></li> </ul>

## POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option for patients aged 16 years and older who have at least one of the following conditions and who have not responded to at least two conventional treatments, (one of which must be pharmacologic interventions of at least two anticholinergics **OR** at least one anticholinergic and one beta-3 adrenergic agonist):
  - A. urge incontinence (unrelated to a neurological condition, see statement IV.B.);
  - B. urgency-frequency syndrome;
  - C. overactive bladder.
- II. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option for patients aged 16 years and older who have chronic, idiopathic, non-obstructive, urinary retention who have either not tolerated, or failed clean-self-catheterization.
- III. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option for patients aged 16 years and older who have fecal incontinence, when **ALL** of the following indications are present:
  - A. Chronic fecal incontinence of greater than two episodes per week with a duration greater than six months (or 12 months, if occurring after vaginal childbirth);
  - B. Documented failure of prescribed conservative therapies (e.g., pharmacologic treatments, dietary changes) performed for more than three months; and

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- C. Incontinence unrelated to an anorectal malformation, chronic inflammatory bowel disease, or neurologic condition such as peripheral neuropathy or complete spinal cord injury.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has not been medically proven to be effective and, therefore, 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; and
  - E. chronic pelvic pain.
- V. Based upon our criteria and assessment of the peer-reviewed literature, bilateral sacral nerve stimulation has not been medically proven to be effective and, therefore, is considered **investigational**.

*Refer to Corporate Medical Policy #1.01.19 Pelvic Floor Stimulation as a Treatment for Urinary or Fecal Incontinence.*

*Refer to Corporate Medical Policy #7.01.66 Radiofrequency Treatment for Fecal Incontinence.*

*Refer to Corporate Medical Policy #8.01.22 Percutaneous Posterior Tibial Nerve Stimulation (PPTNS).*

*Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.*

### **POLICY GUIDELINES**

- I. Prior to permanent implantation, patients must demonstrate an appropriate response to test stimulation. An appropriate response is defined as at least a 50% improvement in voiding/incontinence for both fecal and urinary symptoms, or a 50% decrease in residual urine volume.
- II. Repair and/or replacement of a medically necessary sacral nerve stimulation devices and/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, and
    3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; **AND ONE OF THE FOLLOWING APPLY:**
  - B. *Repair* of the currently used device, when **ALL** of the following are met:
    1. it is no longer functioning adequately,
    2. inadequate function interferes with activities of daily living, and
    3. repair is expected to make the equipment fully functional (as defined by manufacturer); **OR**
  - C. *Replacement* of the currently used device, when the following are met:
    1. it is no longer functioning adequately, **AND EITHER**
    2. has been determined to be non-repairable, or
    3. the cost of the repair is in excess of the replacement cost; **OR**
  - D. *Replacement* of the currently used device, when **BOTH** of the following are met:
    1. there is documentation that a change in the patient's condition makes the present unit non-functional, and
    2. improvement is expected with a replacement unit.
  - E. The *replacement* of properly functioning sacral nerve stimulation devices and/or external components 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.

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### **DESCRIPTION**

Urinary voiding dysfunction is usually defined as the inability to control urination. Urinary voiding disorders are generally divided into five 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 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.

### **RATIONALE**

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

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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 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 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.

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.

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-up 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 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.

### **CODES**

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

#### **CPT Codes**

<b>Code</b>	<b>Description</b>
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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

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<b>Code</b>	<b>Description</b>
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

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<b>Code</b>	<b>Description</b>
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
E0745	Neuromuscular stimulator, electronic shock unit
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

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<b>Code</b>	<b>Description</b>
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****Medically Appropriate Codes:**

<b>Code</b>	<b>Description</b>
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

**ICD10 Codes****Investigational Codes:**

<b>Code</b>	<b>Description</b>
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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\*Key Article

### **KEY WORDS**

Fecal incontinence, Interstim, Neuromodulation, Urge incontinence, Urgency-frequency.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a National Coverage Determination (NCD) for sacral nerve stimulation for urinary incontinence. Please refer to the following NCD website for Medicare Members: [<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>].