

MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|-------------------------|--|
| Medical Policy Title | Sacral Nerve Stimulation |
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| Category | Technology Assessment |
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| Current Effective Date | 10/15/24 |
| Archive Date | N/A |
| Archive Review Date | N/A |
| Product Disclaimer | <ul style="list-style-type: none"> • Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

Sacral Nerve Stimulation for the Treatment of Urinary Conditions

- 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 of age or older when criteria A. and B. or criteria A. and C. are met:
- A. Prior to permanent implantation, the patient must demonstrate an appropriate response to trial stimulation. An appropriate response is defined as at least a 50% improvement in voiding/incontinence and urinary symptoms or a 50% decrease in residual urine volume; and
 - B. Individual has a diagnosis of chronic, idiopathic, non-obstructive, urinary retention who have:
 1. Failed clean-self-catheterization; or
 2. Have not tolerated clean-self- catheterization;

OR
 - C. Individual has a diagnosis of urgency-frequency syndrome, overactive bladder, or urge incontinence that is unrelated to a neurological condition, **and**
 1. Symptoms have persisted for more than six (6) months; **and**
 2. Documentation supports the following:
 - a. failure of conventional treatments (e.g., pelvic floor exercises, lifestyle therapy, bladder training); and
 - b. failure of **ONE** of the following pharmacologic treatments:
 - i. two (2) different anticholinergics; **or**
 - ii. one (1) anticholinergic and one (1) beta-3 adrenergic agonist.

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- II. 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.

Sacral Nerve Stimulation for the Treatment of Fecal Incontinence

- IV. 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. Prior to permanent implantation, the patient must demonstrate 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.
- V. 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;
 - E. Chronic pelvic pain.
- VI. 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**.
- VII. Repair and/or replacement of 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 the 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.

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- VIII. The replacement of properly functioning sacral nerve stimulation devices 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.

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

Refer to Corporate Medical Policy #8.01.22 Tibial Nerve Stimulation for Voiding Dysfunction

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

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 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.

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.

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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.

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.

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 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.

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-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 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

| Code | Description |
|-------|--|
| 64561 | Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement) including image guidance, if performed |

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| Code | Description |
|-------------|---|
| 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 (<i>effective 01/01/24</i>). |
| 0787T | Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator (<i>effective 01/01/24</i>). |
| 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 (<i>effective 01/01/24</i>). |
| 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 (<i>effective 01/01/24</i>). |

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| 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 |
| 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 |

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| Code | Description |
|---------------|--|
| 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)(230.18) for Sacral Nerve Stimulation for Urinary Incontinence. Please refer to the following NCD website for Medicare Members:

[\[http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&\]](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&) accessed 03/18/24.