# Clinical UM Guideline

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| **Subject:** | Sacral Nerve Stimulation for Urinary Retention, Urinary Incontinence, and Fecal Incontinence | | |
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## Description

This document addresses sacral nerve stimulation (SNS) for the treatment of individuals with urinary retention, urinary incontinence, and fecal incontinence.

Urinary retention is the inability to completely empty the bladder. Urinary incontinence is the inability to hold urine in the bladder and can be due to loss of voluntary control over the urinary sphincters resulting in the involuntary passage of urine. Fecal incontinence (FI) is a chronic inability to control bowel function for elimination.

**Note**: Please see the following related documents for additional information:

- CG-DME-04 Transcutaneous Electrical Nerve Stimulation
- CG-MED-97 Biofeedback and Neurofeedback
- CG-SURG-126 Tibial Nerve Stimulation
- SURG.00010 Treatments for Urinary Incontinence
- SURG.00056 Transanal Radiofrequency Treatment of Fecal Incontinence
- SURG.00102 Artificial Anal Sphincter for the Treatment of Severe Fecal Incontinence

**Note:** The use of physical therapy and botulinum toxin is not addressed in this document. Refer to applicable guidelines used by the plan.

## Clinical Indications

**Medically Necessary:**

### I. Sacral Nerve Stimulation for Urinary Urge Incontinence, Urgency/Frequency, and Retention

A trial or temporary sacral nerve stimulator is considered **medically necessary** when the following criteria are met (A *and* B):

A. Any of the following are present and not due to a neurological condition:
   1. Urinary urge incontinence; **or**
   2. Urinary urgency/frequency; **or**

3. Non-obstructive urinary retention;
   **and**

B. Criteria 1 *and* 2 are met:
   1. Clinically significant symptoms are present (for example, frequency or severity impacts ability to work or participate in activities outside of the home); **and**
   2. Symptoms are refractory to, or individual could not tolerate, conservative treatment (for example, medication, pelvic floor muscle exercises, pelvic floor physical exercises with biofeedback, bladder training, or intermittent catheterizations for non-obstructive urinary retention) for at least a sufficient duration to fully assess treatment effect.*****

***** The time frame for prior conservative treatment measures to demonstrate a refractory response is generally considered to be 2 to 3 months' duration, subject to individual variability.

A permanent sacral nerve stimulator is considered **medically necessary** when criteria A *and* B are met:
A. The individual has met criteria above for a trial or temporary sacral nerve stimulator; **and**
B. The individual has demonstrated a successful trial of the temporary sacral nerve stimulator, defined as:
   1. For urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes, or the number of pads/diapers used per day; **or**
   2. For urinary urgency/frequency: At least 50% reduction in the number of voids daily, or 50% increase in volume voided per void; **or**
   3. For urinary retention: At least a 50% reduction in catheter volume/catheterization.

**Not Medically Necessary:**

A sacral nerve stimulator for urinary urge incontinence, urgency/frequency, and non-obstructive retention is considered **not medically necessary** when the medically necessary criteria above have not been met.

## II. Sacral Nerve Stimulation as a Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury

Self-activated electrical stimulation of intact anterior sacral nerve roots using an implantable device (for example, Vocare Bladder System/FineTech Brindley Bladder Control System) to provide urination on demand and reduce post-void residual volume is considered **medically necessary** for individuals who meet all of the following criteria:
A. Have a neurogenic bladder due to a clinically complete** suprasacral spinal cord lesion; **and**
B. Have intact parasympathetic innervation of the bladder; **and**
C. Are skeletally mature and neurologically stable; **and**
D. Cannot be adequately managed with intermittent or condom catheterization.

**As defined by the American Spinal Injury Association (ASIA) Impairment Scale.

**Not Medically Necessary:**

Self-activated electrical stimulation of the anterior sacral roots is considered **not medically necessary** for all other indications.

### III. Sacral Nerve Stimulation for Fecal Incontinence

A trial or temporary sacral nerve stimulator is considered **medically necessary** when the following criteria are met (A *and* B):

A. Treatment is for fecal incontinence; **and**
B. The following are met (1 *and* 2):
    1. Incontinent episodes average greater than or equal to 2 per week for 6 months;† **and**
    2. Symptoms are refractory to, or individual could not tolerate, conventional therapy (for example, dietary modification, addition of bulking agents, pharmacologic treatment) for at least a sufficient duration to fully assess treatment effect.*****

†After vaginal childbirth, most individuals who experience fecal incontinence in the immediate postpartum period will see improvement in symptoms in the year following delivery.

A permanent sacral nerve stimulator is considered **medically necessary** when the following criteria are met:

A. The individual has met the criteria above for a trial or temporary sacral nerve stimulator; **and**
B. The individual has had a successful trial of the temporary sacral nerve stimulator, defined as at least a 50% improvement in symptoms.

### IV. Replacement and Revision of Sacral Nerve stimulators

Replacement or revision of an implanted sacral nerve stimulator (with or without lead changes) is considered **medically necessary** when the current implanted device is no longer functioning appropriately.

**Not Medically Necessary:**

Replacement or revision of an implanted sacral nerve stimulator is considered **not medically necessary** when the medically necessary criteria above for replacement or revision have not been met.

## Coding

*The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

*Sacral Nerve Stimulation*
**When services may be Medically Necessary when criteria are met:**

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| **CPT** | |
| 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) |
| 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 neurostimulator |
| | For the following CPT codes **when specified as a sacral nerve stimulator**: |
| 64585 | Revision or removal of peripheral neurostimulator electrode array [*when specified as a sacral nerve stimulator*] |
| 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 [*when specified as sacral nerve stimulator*] |
| **HCPCS** | |
| | For the following HCPCS codes **when specified as sacral nerve stimulator**: |
| C1767 | Generator, neurostimulator (implantable), nonrechargeable |
| C1820 | Generator, neurostimulator (implantable), with rechargeable battery and charging system |
| C1883 | Adapter/extension, pacing lead or neurostimulator lead (implantable) |
| L8679 | Implantable neurostimulator, pulse generator, any type |
| L8680 | Implantable neurostimulator electrode, each [when specified as a sacral nerve stimulator electrode] |
| L8685 | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension |
| L8686 | Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension |
| **ICD-10 Procedure** | |
| | For the following codes **when specified as sacral nerve stimulator leads**: |
| 01HY0MZ | Insertion of neurostimulator lead into peripheral nerve, open approach |
| 01HY3MZ | Insertion of neurostimulator lead into peripheral nerve, percutaneous approach |
| 01HY4MZ | Insertion of neurostimulator lead into peripheral nerve, percutaneous endoscopic approach |

**ICD-10 Diagnosis**

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| N32.81 | Overactive bladder |
| N39.41-N39.498 | Other specified urinary incontinence |
| R15.0-R15.9 | Fecal incontinence |
| R33.0-R33.9 | Retention of urine |
| R35.0-R35.89 | Polyuria |
| R39.11-R39.198 | Other difficulties with micturition |

**When services are Not Medically Necessary:**
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

*Sacral Nerve Root stimulation*
**When services may be Medically Necessary when criteria are met for sacral root neurostimulators:**

**CPT**

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| 63185 | Laminectomy with rhizotomy, 1 or 2 segments |
| 63190 | Laminectomy with rhizotomy; more than 2 segments |
| 63655 | Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural [when specified as sacral root neurostimulator] |

**HCPCS**

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|---|---|
| L8680 | Implantable neurostimulator electrode, each [when specified as sacral root neurostimulator electrode] |
| L8682 | Implantable neurostimulator radiofrequency receiver [when specified as sacral root neurostimulator] |
| L8684 | Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement |

**ICD-10 Procedure**

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| 018R0ZZ | Division of sacral nerve, open approach |
| 018R3ZZ | Division of sacral nerve, percutaneous approach |
| 018R4ZZ | Division of sacral nerve, percutaneous endoscopic approach |
| 00HU0MZ | Insertion of neurostimulator lead into spinal canal, open approach |
| 00HU3MZ | Insertion of neurostimulator lead into spinal canal, percutaneous approach |
| 00HU4MZ | Insertion of neurostimulator lead into spinal canal, percutaneous endoscopic approach |
| 00HV0MZ | Insertion of neurostimulator lead into spinal cord, open approach |
| 00HV3MZ | Insertion of neurostimulator lead into spinal cord, percutaneous approach |
| 00HV4MZ | Insertion of neurostimulator lead into spinal cord, percutaneous endoscopic approach |

**ICD-10 Diagnosis**

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| | All diagnoses, including but not limited to, |
| N31.0-N31.9 | Neuromuscular dysfunction of bladder, not elsewhere classified |

**When services are Not Medically Necessary:**
For the procedure codes listed above for sacral nerve root stimulators when criteria are not met and for all other indications.

## Discussion/General Information

*Sacral Nerve Stimulation (SNS)*

A sacral nerve stimulator (SNS) is a device that is surgically implanted to treat urinary or fecal incontinence. Use of an SNS includes both a test phase and a second-stage implantation phase.

The test phase involves implantation of a temporary SNS device for a trial period of sacral nerve neuromodulation. This may use either percutaneous nerve stimulation or a temporarily implanted device. This procedure is to confirm the integrity of the peripheral nerves, the feasibility of SNS therapy, to identify the optimal site for a temporary SNS, and to determine anticipated response and candidacy for a permanent device. During the trial, the individual maintains a voiding diary to document their symptoms at baseline and then daily for a 1- to 2-week period while the device is active. The temporary device includes a portable external stimulator, which is carried in the pocket or attached to a belt. The results of the test phase are used to determine whether individuals are appropriate candidates for the permanent SNS device. Pivotal clinical studies assessed both 50% reduction in frequency and 50% increase in volume void per void as endpoints. The rate of adverse events due to SNS is reported as high, and include post-implant pain, infection, adverse changes in bowel function, lead migration, and electric shock sensation. However, most events are minor and resolve with treatment or adjustment to the device.

The InterStim™ System for Urinary Control (Medtronic, Inc., Minneapolis, MN), was investigated in a large multicenter, randomized clinical trial (RCT) that demonstrated that the device was effective in significantly reducing urinary symptoms in those with urge incontinence, urgency/frequency and non-obstructive urinary retention (Hassouna, 2000; Schmidt, 1999). The device was originally cleared by the Food and Drug Administration (FDA) in 1998 for urinary incontinence and received additional labeled clearance for urinary retention in 1999. Additional updated models have obtained FDA clearances; including the Medtronic InterStim Micro rechargeable sacral neuromodulation (SNM) system, which was cleared for the treatment of urge incontinence, urgency/frequency, non-obstructive urinary retention, and chronic fecal incontinence in persons who have failed, or are not candidates for, more conservative treatments (FDA, 2020).

*SNS for Urinary incontinence*

In May 2012, the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) published *Diagnosis and Treatment of Overactive Bladder (Non-*

*Neurogenic) in Adults* and addressed SNS as a recommendation. This document was reissued in 2014 and amended in 2019 (Lightner, 2019) with an updated literature review but no change to the recommendation for SNS, as follows:

> Clinicians may offer sacral neuromodulation (SNS) as third-line treatment in a carefully selected patient population characterized by severe refractory OAB (overactive bladder) symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure. *Recommendation**** (Evidence strength – Grade C; Benefits outweigh risks/burdens).

This determination was based upon the following guideline discussion:

> Given the negative effects on quality of life associated with severe incontinence and frequency, the Panel judged that benefits of SNS in the appropriate patient outweighed the risks/burdens and notes that patients should be carefully counseled regarding the risks/burdens. Evidence strength is Grade C because of the predominance of observational designs, the small sample sizes, the limited number of unique patient groups (i.e., there are multiple reports on the same patient groups followed over time) and limited information regarding the protocols used by patients to maintain symptom control.

***Note:** According to the AUA, use of the nomenclature, "Recommendation" is defined as: "Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C (low quality; low certainty) evidence."

It was further noted in the updated literature review that:

> SNS studies reported frequent adverse events, including pain at the stimulator site (3.3 to 19.8% of patients), pain at the lead site (4.5 to 19.1% of patients), lead migration (1.1 to 2.2, 8.6% of patients), infection/irritation (2.2 to 14.30% of patients), electric shock (5.5 to 10.2, 7.9% of patients) and need for surgical revision (6.25 to 39.5% of patients). In most studies, the need for surgical revision occurred in greater than 30% of patients.

On November 13, 2019, the Axonics Sacral Neuromodulation (SNM) System (Axonics Modulation Technologies, Inc. Irvine, CA) was cleared by the FDA for, "The treatment of urinary retention and the symptoms of overactive bladder (OAB), including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments." This clearance was subject to periodic post-approval safety reports to be submitted to the FDA.

*SNS for Overactive Bladder*

In 2022, Chartier-Kastler reported the 3-year results of the SOUNDS (Sacral neuromOdUlation with InterStim therapy for intractable lower uriNary tract DySfunctions) prospective observational study involving 291 participants with OAB treated with SNS. Participants included those with urge-frequency (dry) and urinary urge incontinence (wet) OAB. Participants received a de novo (n=139) or replacement (n=51) InterStim device and had four follow-up visits two within the first year and annually thereafter. A fourth follow-up visit was achieved by 190 participants after a mean of 33.7 months. Both the mean number of voids per day for the dry OAB group and leaks per day for the wet OAB group were significantly lower at all follow-up visits, except at 21 months for the dry OAB participants who received a replacement device subgroup (p=0.05). Therapy responder rates in the UI cohort at 34 months were 72% and 86% in the de novo and replacement groups, respectively, and complete continence was achieved in 30% of the de novo group and 50% of the replacement group. There were statistically significant improvements in the OAB-specific domain of the Urinary Symptom Profile (USP2) at all visits for both the de novo and replacement groups (all p<0.001). The device- or procedure-related adverse event rate was 49%, with the most frequent events reported being implant site pain (6%), implant site infection (4%), battery-related events (5%), device use error (5%), and device failure (7%). The most frequent action taken to address adverse events was reprogramming of the device. Overall, 12% of participants experienced a serious adverse event, which were most frequently addressed by removal of the lead (11%) or neurostimulator (8%), reprogramming the device (7%), or antibiotic (6%) or analgesic treatment (4%). Surgical revisions, including replacement, repositioning, or temporary or permanent removal of one or more components of the system was reported in 33% of participants who had received a full system. Permanent device removal occurred in 13% of participants. The authors concluded that SNS resulted in significant reductions in both daily voids and leaks participants with OAB. They also stated, "the therapy safety profile was in agreement with published literature. Although the majority of ADEs were classified as minor, this remains an area for which further improvements are desirable through procedural modifications and technical advances."

*SNS for Neurogenic Bladder Secondary to Spinal Cord Injury*

Spinal cord injury (SCI) can result in varying degrees of neurological impairment depending on the location and severity of the injury. The American Spinal Injury Association (ASIA) Impairment Scale is a system used to classify or describe the extent of spinal cord injuries. The classification is as follows:

- **A = Complete:** No motor and sensory function is preserved in the sacral segments S4-S5.
- **B = Incomplete:** Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5.
- **C = Incomplete:** Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3.
- **D = Incomplete:** Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more.
- **E = Normal:** Motor and sensory function are normal.

Supra-sacral spinal cord injury may result in neurogenic bladder, characterized in part by frequent urinary tract infections from inadequate bladder emptying. The high bladder pressures related to large post-void residuals can lead to autonomic dysreflexia, vesicoureteral reflux, upper urinary tract dilations, hydronephrosis, and eventual renal failure.

Sacral anterior root stimulation is intended to provide bladder evacuation by delivering electrical stimulation to intact spinal nerve roots in order to produce functional contraction of the innervated muscles. Implantation of a sacral anterior root stimulator is typically performed in conjunction with a simultaneous posterior rhizotomy. The rhizotomy results in an areflexive bladder with low intravesicular pressure and high compliance. When the user activates the implanted stimulator, the urethral sphincter and bladder contract and relax, allowing the bladder to empty on demand with low residual urine volumes.

The Vocare Bladder System (Finetech Medical, Hertfordshire, UK) has received approval by the Food and Drug Administration (FDA) for stimulation of the sacral anterior nerve root. Outside of the United States, the device is known as the Finetech-Brindley device. The FDA-labeled indication, approved in 1999, included the following:

> The Neurocontrol Vocare Bladder System is indicated for the treatment of patients who have clinically complete spinal cord lesions with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce post-void residual volumes of urine.

Intact parasympathetic innervation of the bladder is described by the manufacturer as having "intact reflex bladder contractions" (Finetech Medical, 2021). The Vocare package insert further specified:

> Prior to implant, patients should show reflex bladder contraction with an increase in detrusor pressures over baseline of at least 35 cm H20 in women and 50 cm H20 in men during cystometry. This ensures that parasympathetic preganglionic neurons from the conus medullaris to the bladder are intact.

The Vocare Bladder System consists of the following implantable external and surgical components:

- Implanted components consist of the implantable receiver-stimulator, which is implanted subcutaneously. The receiver-stimulator is attached to extradural electrodes that are attached to the sacral anterior nerve roots.
- External components consist principally of an external, battery-powered controller and transmitter. The external controller generates and delivers a sequence of electrical pulses that are emitted as electromagnetic fields from the transmitter. The transmitter is placed on the skin over the subcutaneously implanted receiver-stimulator.
- The surgical components include a variety of surgical tools to assist in the identification of the appropriate nerve roots for posterior rhizotomy and the optimal placement of the implanted extradural electrodes.
- Posterior rhizotomy requires a S1-S3 laminectomy. The extradural electrodes are implanted during the same procedure.

The Vocare Bladder System received FDA approval through a Humanitarian Device Exemption and as such, randomized controlled trials (RCTs) were not required for approval. The FDA approval was based on the Creasey (2001) prospective trial. The study included 23 individuals with complete suprasacral spinal cord injuries who underwent implantation of the device in association with posterior rhizotomy and were followed for a minimum of 3 months. Comparisons were made with the device turned on and off; thus participants served as their own controls. There was a significant improvement in bladder emptying, as measured by voided volumes and post void residual, when the device was turned on compared with the off condition. For example, at 3 months, 19 of 21 individuals (91%) for whom data were available voided more than 200 mL of urine on demand with the device turned on versus no participants voiding more than 200 mL of urine with the device turned off. Diary data at 12 months were available for 17 participants; of these, 12 reported a reduction in urinary incontinence.

Ren and colleagues (2015) performed a literature review of electrical nerve stimulation used for promotion of micturition in individuals with spinal cord injuries. There were no RCTs or other controlled trials found. The authors identified 14 uncontrolled studies using Brindley devices published between 1982 and 2013. Continence rates ranged from 59% to 93%. Review authors did not pool study findings. However, they concluded that "electrical nerve stimulation, mainly conducted with the Finetech-Brindley stimulator, is a considerable option for bladder management in SCI patients." As noted above, the Finetech-Brindley device is branded as Vocare in the United States.

*SNS for Fecal incontinence*

The Food and Drug Administration (FDA) cleared the Interstim Therapy (Medtronic, Inc., O'Fallon, IL) device for the application of the treatment of fecal incontinence (FI) on March 14, 2011, subject to a 5-year post-approval study with the primary objective to continue evaluation of incontinent episodes per week at yearly intervals through 5 years post-implant. Both device and therapy adverse events were tracked during this study period. In 2011, Mellgren and colleagues submitted some ongoing results for the FDA post approval study. A total of 83 participants completed part or all of the assessment. Perfect continence was reported by 40% of study participants. Improvements in the Fecal Incontinence Quality of Life scale were reported at 12, 24 and 36 months of follow-up. Adverse events included implant site pain (28%), paresthesia (15%), change in the sensation of stimulation (12%), and infection (10%). The authors stated 77 of 120 participants (64%) completed a bowel diary assessment at the 3-year follow-up. While there were a large number of trial participants who were lost to follow-up (n=43), there was good continence control noted in 40% of trial participants.

In 2017, the American Gastroenterological Association (AGA, Bharucha, 2017) released an updated clinical practice guideline for fecal incontinence and defectory disorders. That document stated:

> Sacral nerve stimulation should be considered for patients with moderate or severe FI in whom symptoms have not responded after a 3-month or longer trial of conservative measures and biofeedback therapy and who do not have contraindications to these procedures.

On September 6, 2019, the FDA cleared another device, the Axonics r-SNM® System, which is another rechargeable SNM system. This device is indicated for, "The treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments." This approval is contingent upon submissions of annual safety reports including any adverse events associated with the device (FDA, 2019).

Wexner and colleagues (2010) reported results from a prospective, multicenter study of SNS for fecal incontinence. Inclusion criteria were refractory fecal incontinence averaging 2 episodes per week for 6 months or for 12 months after vaginal delivery. Excluded were those who had previous rectal surgery, if performed within the last 12 months (or within 24 months in cases of cancer); defects of the external anal sphincter over 60 degrees; chronic inflammatory bowel disease; visible sequelae of pelvic radiation; active anal abscesses and fistulae; neurologic diseases such as clinically significant peripheral neuropathy or complete spinal-cord injury; and anatomic limitations preventing the successful placement of an electrode. Out of 285 participants evaluated, 120 participants underwent preliminary test stimulation procedures and showed a greater than or equal to 50% improvement. This group went on to receive a permanent stimulator. A 50% or better improvement was seen in 106 participants at 12 months, 67 participants at 24 months and 30 participants at 36 months, based on records of incontinent episodes. Further analysis showed that 40% of the 106 participants at the 12-month follow-up reported complete continence.

In 2023, the American Society of Colon and Rectal Surgeons (ASCRS, Bordeianou, 2023) released an updated clinical practice guideline for the treatment of fecal incontinence. They stated, "Sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects (strength of recommendation, conditional; GRADE quality of evidence, low)."

Eggers (2024) conducted a systematic review addressing the long-term outcomes of SNS for FI. They included 3370 individuals and 36 studies and showed an overall improvement in objective and subjective outcomes at ≥ 36 months. Success rates, as defined by individual studies, varied from 20.9% to 87.5% among permanent implants. Most studies also reported significant improvements in symptom severity scores (Cleveland Clinic Incontinence Score [CCIS], the St Mark's Incontinence Score [SMIS], and the Fecal Incontinence Severity Index [FISI]) and QOL, suggesting that SNS may be an effective long-term treatment for FI.

Park (2024) reported the results of a prospective cohort study of SNS in 65 participants under 21 years of age with functional and/or organic defecation disorders resulting in constipation and/or FI. Thirty (46%) participants had constipation and 15 (23%) had FI. Participants had heterogeneous etiologies, including anorectal malformation (ARM, n=16), Hirschsprung disease (n=1), and spinal cord abnormalities (n=9). Data was collected at 1, 6, 12, 24, 36, 48, and ≥ 60 months after starting SNS. The majority of participants had bowel movements (BMs) > 2 times per week at baseline. No significant change in this metric was reported over the course of the study. The percentage of participants with FI < 1 time per week improved significantly, from 30% at baseline to 77% at most recent follow-up visit ($p<0.000$). Of the children with follow-up data at ≥ 60 months, 86% had FI (n=15, $p< 0.001$). Self-reported scores on the PedsQL Gastrointestinal Symptoms Scale (GSS) and Cleveland Clinic Constipation Score (CCCS) improved significantly from baseline to most recent follow-up ($p<0.001$ and $p=0.02$, respectively). Fecal

incontinence severity, as measured by the FISI, was also reported to have improved significantly by the most recent follow-up (p=0.03). The number of medications and suppositories used did not change significantly over the course of the study. At most recent follow-up, the number of participants reporting regular use of antegrade continence enema (ACE) decreased significantly (p=0.03). Similarly, the frequency of ACE also decreased, from a median of 6–7 days per week at baseline to 1 day per week at most recent follow-up (p=0.002). Improvement in FI was noted in all participants with constipation, non-retentive fecal incontinence (NRFI), or ARM, with the largest improvement seen in children with constipation (p=0.02, p<0.001, and p=0.02, respectively). The authors reported that at the most recent follow-up visit, 77% (34/44) of participants with a functional disorder (constipation or NRFI) and 50% (10/20) of participants with an organic cause of constipation or FI met criteria for a successful response to SNS treatment. Complications due to SNS were reported in 22 (34%) participants. Seven developed a wound infection requiring device removal and replacement (n=4), permanent removal (n=2), or debridement (n=1). Six experienced pain or discomfort related to SNS, requiring repositioning of the device (n=3), lead replacement (n=2), or removal and replacement (n=1). Nine had no response to SNS, leading to repositioning of the device (n=3), lead replacement (n=2), or permanent removal (n=2). Two of these non-responders had their SNS turned off at most recent follow-up. Overall, complications resulted in a total of 24 surgeries and 4 permanent SNS removals. The authors concluded that SNS led to sustained improvement in FI regardless of underlying etiology. They also noted that participants with functional disorders were more likely to respond than those with organic disorders.

While the literature supports SNS for fecal incontinence, the adverse event occurrence is high. Additionally, degree of success varies among the eligible population. Careful selection of individuals for this treatment is important (Mowat, 2008). Information regarding the benefits and risks should be discussed so that suitable individuals can make an informed decision. It is notable that most individuals who experience fecal incontinence in the immediate postpartum period will see improvement in symptoms in the year following delivery and can avoid treatment with SNS.

## Definitions

Intrinsic sphincter deficiency (ISD): Stress incontinence caused by weakness of the urinary sphincter (a ring-like band of muscle fibers that constrict or close the natural opening to the bladder).

Neuromodulation: A technology that alters (or modulates) nerve activity using electrical stimulation or pharmaceutical agents..

Overactive bladder syndrome (OAB): A general term used to describe urinary urgency, usually with urinary frequency and nocturia, with or without urgency/urinary incontinence. In most cases, the cause of the OAB is unknown. In some cases, it is associated with neurological conditions, such as multiple sclerosis or Parkinson's disease.

Sacral nerve: Any of five pairs of spinal nerves in the sacral region which innervate muscles and skin of the lower back, lower extremities, and perineum, and branches to the hypogastric and pelvic plexuses.

Sacral nerve stimulation: A permanent implantable device that stimulates the neural pathways controlling bladder function.

Stress urinary incontinence (SUI): The leakage of urine during physical activities that increase pressure on the bladder.

Urethra: The natural channel or tube through which urine passes from the bladder to outside of the body.

Urinary retention: The inability to completely empty the bladder of urine.

Urinary urge incontinence: Leakage of urine when there is a strong urge to void.

Urinary urgency-frequency: An uncontrollable urge to urinate resulting in very frequent, small volumes.

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## Index

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**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## History

| Status | Date | Action |
|---|---|---|
| Revised | 02/20/2025 | Medical Policy & Technology Assessment Committee (MPTAC) review. Revised title. Moved content related to tibial nerve stimulation to new document CG-SURG-126. Added content for sacral nerve stimulation from CG-SURG-08 Sacral Nerve Stimulation as a Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury. Revised Description, Clinical Indications, Discussion, Definitions, References, Websites, and Index sections. Revised Coding section to add 63185, 63190, 63655, L8682, L8684 and associated ICD-10-PCS codes, and removed codes 0587T, 0588T, 0816T, 0817T, 0818T, 0819T, and 64566 related to tibial nerve stimulation. |
| Revised | 11/14/2024 | MPTAC review. Revised formatting in Clinical Indications section. Updated Discussion, References, and Websites for Additional Information sections. |
| Revised | 11/09/2023 | MPTAC review. Revised formatting of Clinical Indications section. Revised MN criteria for trial sacral nerve stimulators for urinary incontinence/urgency/frequency and retention to add new examples of conservative treatments. Revised permanent sacral nerve stimulators MN criteria for urinary urgency/frequency. Revised sacral nerve stimulation NMN statement. Added new MN criteria for percutaneous and implantable tibial nerve stimulation. Added new MN and NMN criteria for replacement or revision of percutaneous and Implantable tibial nerve stimulators. Revised percutaneous and implantable tibial nerve stimulation NMN statement. Updated Description, Discussion, References, Websites for Additional Information, and Index sections. Updated Coding section to include 01/01/2024 CPT changes; added 0786T, 0787T, 0816T, 0817T, 0818T, 0819T and revised descriptors for 64590, 0587T, 0588T; also removed 0589T, 0590T no longer applicable. |
| Revised | 05/11/2023 | MPTAC review. Added MN criteria for the temporary SNS for urinary and fecal conditions. Reformatted the MN criteria for permanent SNS for urinary and fecal conditions. Revised the title, description and Clinical Indications |

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|---|---|---|
| | | section IV for PTNS to include implantable devices. Updated the Discussion, Coding and References sections. |
| Revised | 05/12/2022 | MPTAC review. The requirement for a 12-month history of symptoms post vaginal delivery for SNS in FI was removed from criteria and clarified in a Note. Criteria for when replacements and revisions to SNS devices are MN were added. The Rationale and References sections were updated. Updated Coding section, added code 64585. |
| Reviewed | 02/17/2022 | MPTAC review. The Discussion and Reference sections were updated. |
| | 12/29/2021 | Updated Coding section with 01/01/2022 CPT descriptor change for 64581. |
| | 10/01/2021 | Updated Coding section with 10/01/2021 ICD-10-CM changes; added R35.89 replacing R35.8 deleted 09/30/2021. |
| Revised | 02/11/2021 | MPTAC review. The Clinical Indications and criteria were reformatted for clarification and statements about temporary SNS and trial periods were removed. The Discussion and References sections were updated. |
| Reviewed | 11/05/2020 | MPTAC review. References and Index sections were updated. Reformatted Coding section; added HCPCS codes C1820, C1883, L8685 and ICD-10-CM diagnosis R10.2. |
| | 10/01/2020 | Updated Coding section with 10/01/2020 ICD-10-CM changes; added K59.81-K59.89 replacing K59.8 deleted 09/30/2020. |
| Reviewed | 11/07/2019 | MPTAC review. The Discussion, Index and References sections were updated. Updated Coding section with 01/01/2020 CPT changes; added 0587T, 0588T, 0589T, 0590T. |
| New | 01/24/2019 | MPTAC review. Moved content of SURG.000117 Sacral Nerve Stimulation and Percutaneous Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention to a new clinical utilization management guideline document with the same title. Removed acronyms from the Title and Clinical Indications section. The References section was updated. |