

## Sacral Nerve Stimulation for Pelvic Floor Dysfunction

**Policy** MP-076

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**Current Effective Date:** 03/20/2024

### Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

### Description:

Urinary voiding dysfunction is usually defined as the inability to control urination and is divided into different types:

- **Overactive bladder (OAB):** The International Continence Society has defined overactive bladder syndrome as "urinary urgency, usually with increased daytime frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry) urgency urinary incontinence, in the absence of urinary tract infection or other detectable disease".
- **Urinary urge incontinence:** Is defined as the involuntary leakage of urine when there is a strong urge to void due to bladder spasms or contractions with enough force to override the sphincter muscles of the urethra.
- **Urinary urgency-frequency incontinence:** Is defined as strong and abnormal urge to urinate, resulting in frequent urination without a loss of the feeling of the fullness of the bladder.
- **Non-obstructed urinary retention:** Is usually caused by weak pelvic floor muscles or dysfunction in the neural pathway between the brain and bladder and results in the inability to completely empty the bladder of urine.

Fecal incontinence is the involuntary loss of flatus, liquid, or stool. Fecal incontinence (FI) may be caused by diarrhea, fecal impaction, damage to the anal sphincter (e.g., childbirth, surgery), or illnesses that cause the inability to expand and store fecal matter (e.g., inflammatory bowel disease [IBD], Crohn's disease or injury). Although it is considered a benign disorder, severe FI is

a distressing and socially isolating medical condition. Individuals who suffer from this condition often alter their lifestyle to minimize the likelihood of bowel accidents in public places. Over time, this can result in progressive social isolation and work incapacity.

The majority of cases of FI are mild-to-moderate and can be managed with medical interventions including anti-diarrheal medications, treatment of underlying infections or inflammatory disorders as indicated, pelvic floor biofeedback, defecation programs (bowel training) and dietary management.

Treatment using sacral nerve stimulation (SNS) or sacral nerve neuromodulation (SNM) is one of several alternative modalities for patients with urinary or fecal incontinence (urge incontinence, significant symptoms of urgency-frequency, nonobstructive urinary retention) who have documented failure or intolerance to conventional conservative therapies like behavioral and/or pharmacologic therapies.

The SNS/SNM device consists of an implantable pulse generator that delivers controlled electrical impulses. This generator is attached to wire leads that connect to the sacral nerves. Two external components of the system help control the electrical stimulation. The patient uses a control magnet to turn the device on or off and the physician is given a console programmer used to adjust the settings of the pulse generator.

Before implantation of the permanent device, patients undergo an initial testing phase, which is called percutaneous nerve evaluation (PNE), to estimate potential response to treatment. PNE 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 that is connected to an external stimulator is inserted through the test needle and left in place for 4 to 7 days. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device.

The second type of testing is a two-stage surgical procedure. In the first stage, a quadripolar tinted lead is implanted. This testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, they can proceed to stage 2 of the surgery, which is permanent implantation of the neuromodulation device.

## **Policy Statement and Criteria**

### **1. Commercial Plans/CHIP**

#### *Urinary Incontinence*

**U of U Health Plans considers a trial period of sacral nerve stimulation (neuromodulation) for urinary incontinence, with a temporarily implanted lead or percutaneous nerve stimulation medically necessary when ALL of the following criteria are met (A-D):**

- A. There is a diagnosis of at least one of the following:
  - i. Urge incontinence;

- ii. Urgency-frequency syndrome;
  - iii. Non-obstructive urinary retention;
  - iv. Overactive bladder;
- B. Documentation showing contraindication, failure or intolerance over a period of 12 consecutive months, to at least 2 conventional therapies, (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, onabotulinumtoxinA injections, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy);
- C. The member is a surgical candidate;
- D. Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition (such as multiple sclerosis or diabetic neuropathy).

**U of U Health Plans considers permanent implantation of a sacral nerve neuromodulation device for urinary incontinence may be considered medically necessary in patients who meet ALL of the following criteria:**

- A. All of the trial period criteria above have been met;
- B. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

***Fecal Incontinence (FI)***

**U of U Health Plans considers a trial period of sacral nerve stimulation (neuromodulation) for fecal incontinence, with a temporarily implanted lead or percutaneous nerve stimulation medically necessary when ALL of the following criteria are met (A-F):**

- A. The patient is an appropriate surgical candidate;
- B. There is a diagnosis of chronic fecal incontinence of more than 2 incontinent episodes on average per week for more than 6 months, or for more than 12 months after vaginal childbirth;
- C. There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy;
- D. The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees;

visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease;

- E. Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition (such as multiple sclerosis or diabetic neuropathy);
- F. The patient has not had rectal surgery in the previous 12 months, or in the case of rectal cancer, the patient has not had rectal surgery in the past 24 months.

**U of U Health Plans considers permanent implantation of a sacral nerve neuromodulation device for fecal incontinence may be considered medically necessary in patients who meet ALL of the following criteria:**

- A. All of the criteria above are met;
- B. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

**U of U Health Plans considers all other urinary/voiding applications of sacral nerve neuromodulation investigational, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury or other types of chronic voiding dysfunction).**

**U of U Health Plans considers sacral nerve neuromodulation investigational in the treatment of chronic constipation or chronic pelvic pain.**

## **2. Medicaid Plans**

**Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)**

**CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.**

## **Clinical Rationale**

### **Urinary Incontinence**

UpToDate recently examined sacral nerve stimulation (SNS) as a treatment for urgency urinary incontinence/overactive bladder (OAB) in females (Lukacz, 2023). The review determined that “Sacral

neuromodulation (SNM) is a minimally invasive surgical electrical stimulation option to treat OAB symptoms that is offered to patients whose symptoms do not respond to initial interventions and pharmacotherapy. Several devices are available, including InterStim micro® system, InterStim II®, and Axonics®, which include MRI-compatible options. InterStim micro and Axonics have rechargeable implanted programmable device options, which can increase battery life to 15 years or more and may be more cost-effective than the non-rechargeable option. These devices require the patient to have the cognitive ability and desire to manage the technology, perform a testing procedure; monitor the impact of stimulation on urinary incontinence episodes, urgency, and pad usage for a week or two; and manage the recharging process should they select this option. The InterStim II device has a non-rechargeable battery that requires replacement every 3 to 5 years". Comparison with botulinum toxin injections – A trial comparing onabotulinumtoxinA and SNM (InterStim) in female patients with refractory urge incontinence reported a statistically greater reduction in incontinence episodes for the onabotulinumtoxinA group (-3.9 versus -3.3 urgency urinary incontinence episodes per day, mean difference 0.63, 95% CI 0.13-1.14).

In 2022 Hayes performed a health tech assessment pertaining to SNS for the treatment of non-obstructive urinary retention (NOUR) in adults and concluded that "Patients who have chronic refractory NOUR may have a strong interest in SNS therapy but need to be aware that some patients are not candidates for this therapy due to inadequate response during initial testing and that many patients obtain partial, rather than complete, relief of symptoms after implantation of a permanent stimulator system. Despite the low quality of the evidence, SNS may be a reasonable treatment option for patients with intractable NOUR who have not responded adequately to standard therapies or alternative therapies and who meet the criteria for permanent implantation."

A 2021 expert review of medical devices (Wang et al) determined that over-active bladder (OAB) and urgency urinary incontinence (UUI) affect millions of women and men and results in billions of dollars in health-care expenses. First- and 2nd-line therapy includes behavioral modifications and/or pharmacotherapies; however, many patients' symptoms remain or worsen on these treatments. There has been concern regarding the detrimental side effects of the most widely prescribed medications for these bladder symptom management. As a result, there has been increased interest in continuous sacral neuromodulation, a U. S. Food and Drug Administration (FDA)-approved therapy for refractory UUI. These investigators reviewed current research on the effectiveness, patient/provider satisfaction and safety profile of the Axonics System along with the current state of SNM, its potential future direction and applicability. The authors concluded that the Axonics system is a safe and effective device for the treatment of OAB and UUI. It affords patients the convenience of a rechargeable, compact, magnetic resonance imaging (MRI) safe system. Also, this system is easily adapted for experienced implanters of sacral neuromodulating devices. However, the rechargeable system, while allowing for approximately 15 years of battery and lead life, may have its challenges in terms of charge burden.

Also in 2021, Pezzella et al presented 2-year follow-up results and determined that SNM is a guideline-recommended treatment with proven therapeutic benefit for UUI patients. The Axonics® System is the 1st FDA-approved rechargeable SNM system and is designed to deliver therapy for a minimum of 15 years. The Axonics SacRal Neuromodulation System for Urinary Urgency Incontinence Treatment (ARTISAN-SNM) study evaluated 129 UUI participants who underwent implantation with the Axonics System. Therapeutic response rate, participant quality of life (QoL), and satisfaction were determined using 3-day voiding diaries, ICIQ-OABqol, and satisfaction questionnaires. Participants were considered responders if they had a 50% or greater reduction in UUI episodes post-treatment. At 2 years, 93 % of the participants (n = 121 completers at 2 years) were therapy responders, of which 82% achieved greater than or equal to 75% reduction in UUI episodes and 37% were dry (100% reduction). Daily UUI

episodes reduced from  $5.6 \pm 0.3$  at baseline to  $1.0 \pm 0.2$  at 2 years. Statistically significant improvements in ICIQ-OABqol were reported. All participants were able to recharge their device and 94% of participants reported that the recharging frequency and duration were acceptable. Participant demographics nor condition severity were correlated with clinical outcomes or recharging experience. No unanticipated or serious device-related AEs occurred. The authors found that at 2 years, participants treated with the Axonics System demonstrated sustained safety and effectiveness, high levels of satisfaction with therapy and recharging. However, participant-related factors were not associated with effectiveness or recharging outcomes, indicating the reported results were applicable to a diverse population.

In a 2016 prospective, multicenter post-approval study, Noblett et al evaluated the success rate at 12 month follow-up of the InSite trial. The authors included patients from the initial RCT in the SNM group plus additional patients enrolled and implanted in the interim. A total of 340 patients underwent test stimulation, 272 underwent implantation, and 255 completed 12 months of follow-up. The Modified Completers dataset showed a therapeutic success rate of 82% and included patients who received a full system implant and had either a baseline or 12-month evaluation or withdrew from the trial due to a device-related adverse event or lack of efficacy resulting in explant. In an analysis limited to study completers, the therapeutic response rate was 85%. The authors concluded that SNM resulted in improved outcomes that were safe and effective, through 12 months in subjects with OAB symptoms. However, this study did not include data from the control group of patients receiving only standard medical therapy.

Shamliyan conducted an assessment of nonsurgical treatments for urinary incontinence for the Agency for Healthcare Research and Quality (AHRQ) in 2012 and found that intravaginal electrical stimulation increased continence rates and improved stress urinary incontinence more often than sham stimulation. This assessment was based upon nine studies that examined intravaginal electrical stimulation. The studies included women with predominant urgency UI, clinical or urodynamic stress UI, or urodynamic mixed UI. Electrical stimulation was described with different levels of detail and had variable stimulation parameters, depending on the UI type being treated, including the use of 4 Hz, 10 Hz, 20 Hz, or 50 Hz frequency for 4 weeks, 7 to 8 weeks, 12 weeks, or 15 weeks. The authors concluded that a high level of evidence suggests increased continence rates and improvement in UI with electrical stimulation.

In 2013, the NICE guideline for Urinary Incontinence: The Management of Urinary Incontinence in Women provided the following recommendations regarding urodynamic testing:

1. Do not perform multi-channel cystometry, ambulatory urodynamics, or video urodynamics before starting conservative management.
2. After undertaking a detailed clinical history and examination, perform multi-channel filling and voiding cystometry before surgery in women who have:
  - a) Symptoms of over-active bladder leading to a clinical suspicion of detrusor over-activity, or
  - b) Symptoms suggestive of voiding dysfunction or anterior compartment prolapse, or
  - c) Had previous surgery for stress incontinence.
3. Do not perform multi-channel filling and voiding cystometry in the small group of women where pure SUI is diagnosed based on a detailed clinical history and examination.
4. Consider ambulatory urodynamics or video urodynamics if the diagnosis is unclear after conventional urodynamics.

The American College of Obstetricians and Gynecologists (ACOG) also published in their practice bulletin (#155) on urinary incontinence from 2015 support for SNS stating, "Sacral neuromodulation may be

considered for patients with recalcitrant urinary urge incontinence who have failed other conservative measures, including bladder training, pelvic floor physical therapy with biofeedback, and pharmacologic treatment.”

Several guidelines have also been published in support of SNS. In 2018, the International Continence Society’s (ICS) best practice statement for use of sacral stimulation concluded that sacral neuromodulation is effective for NOUR based on high-quality evidence. This statement also reports that moderate-quality evidence has shown the trial phase of SNS to be the single best tool for predicting therapeutic success for urological indications (Goldman et al.).

The American Urological Association (AUA) 2019 guidelines for OAB state: “Clinicians may perform multi-channel filling cystometry when it is important to determine if altered compliance, detrusor over activity (DO) or other urodynamic abnormalities are present (or not) in patients with urgency incontinence in whom invasive, potentially morbid or irreversible treatments are considered” and that “Clinicians may offer sacral neuromodulation (SNS) as third-line treatment in a carefully selected patient population characterized by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure.” This recommendation, however, was given an evidence strength grade C; benefits outweigh risk/burdens.

In 2022 the European Association of Urology (EAU) developed guidelines for diagnosing and managing non-neurogenic female lower urinary tract symptoms (LUTS). This report covers recommendations associated with LUTS and the treatment of OAB, stress UI, and mixed UI. Updated literature searches were conducted in September 2021, and evidence synthesis was carried out using the modified GRADE criteria outlined for all EAU guidelines. The recommendations outlined in this guideline related to SNS for treatment of LUTS are: Offer SNS to individuals who have OAB/UUI refractory to anticholinergic therapy, and life-long surveillance to women with an SNS implant to monitor for lead displacement, malfunction, and battery wear. This guideline was developed with the grade of recommendation: strong recommendation based on moderate-quality evidence, 1B (Nambiar et al., 2022).

### Fecal Incontinence

A recent UpToDate review (2023) on “Fecal incontinence in adults: Management” stated that “For patients who fail to respond to initial management, options include biofeedback, injectable anal bulking agent, sacral nerve stimulation, and anal sphincteroplasty.... We reserve sacral nerve stimulation for patients who fail conservative management and pelvic floor physical therapy.”

Multiple published studies have supported SNS for fecal incontinence. A 2010 key multicenter prospective trial (Wexner et al) is the 16-site FDA investigational device exemption study of SNS in 120 patients with fecal incontinence. Criteria for the study included, patients with chronic fecal incontinence for more than 6 months or more than 12 months after vaginal childbirth, defined as more than 2 incontinent episodes on average per week and patients who had failed or were not candidates for more conservative treatments. Exclusion criteria included congenital anorectal malformation; previous rectal surgery, if performed within the last 12 months (or 24 months in case of cancer); defects of the external anal sphincter over 60°; chronic inflammatory bowel disease; visible sequelae of pelvic radiotherapy; 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. A total of 285 patients were screened; 133 were enrolled and underwent acute test stimulation, and 120 showed at least 50% improvement during the test phase and received a permanent stimulator. Thirty-four of the 120 patients exited the study for various reasons both related (ie, lack of efficacy in 6, implant site infection or skin irritation in 5) and unrelated to the implant (i.e., the death of a local principal investigator). Analysis based on the initial 133 patients showed a 66%

success rate ( $\geq 50\%$  improvement), while analysis based on 106 patients considered completed cases at 12 months showed an 83% success rate. The success rate based on the 120 patients who received a permanently implanted stimulator would fall between these 2 rates. Of 106 cases included in the 12-month results, perfect continence (100% improvement) was reported in approximately 40%, while an additional 30% of patients achieved 75% or greater reduction in incontinent episodes. Success was lower in patients with an internal anal sphincter defect (65% [n=20]) than in patients without a defect (87% [n=86]). The authors concluded that SNS using InterStim Therapy is a safe and effective treatment for patients with FI.

In a 2011 multicenter study, Mellgren et al assessed 120 patients who received a permanently implanted stimulator for FI. Mean length of follow-up was 3.1 years, and 83 (69%) completed at least part of the 3-year follow-up assessment. In ITT analysis using the last observation carried forward, 79% of patients experienced at least a 50% reduction in the number of incontinent episodes per week compared with baseline, and 74% experienced at least a 50% reduction in the number of incontinent days per week. In a per-protocol analysis at 3 years, 86% of patients experienced at least a 50% reduction in the number of incontinent episodes per week, and 78% experienced at least a 50% reduction in the number of incontinent days per week. By the 3-year follow-up, 334 adverse events considered potentially device-related had been reported in 99 patients; 67% of these occurred within the first year. The most frequently reported adverse events among the 120 patients were implant site pain (28%), paresthesia (15%), implant site infection (10%), diarrhea (6%), and extremity pain (6%). Six infections required surgical intervention (5 device removals, 1 device replacement). In conclusion, long-term safety and effectiveness using the SNS InterStim<sup>®</sup> device proved to be a safe and effective treatment for patients with FI at the 36 months follow-up.

Another study also reported on long-term outcomes (minimum, 60-month follow-up; median, 84-month follow-up) in patients implanted with a SNS for FI (Altomare et. al., 2015). Patients were identified from a European registry and surveyed. Long-term success was defined as maintaining the temporary stimulation success criteria, i.e., at least 50% reduction in the number of fecal incontinence episodes (or fecal incontinence symptom score) at last follow-up, compared with baseline. A total of 272 patients underwent permanent implantation of an SNS device, and 228 were available for follow-up. The authors concluded that a total of 194 (71.3%) of the 272 patients with implants, maintained improvement in the long-term.

In 2020, an observational study (Leo et.al), prospectively evaluated long-term function with SNS for FI from 1996 to 2014 (N=256). The median incontinence score improved from 19/24 at baseline to 7/24 at the 6-month follow-up. Of the total cohort, 235 patients were followed for a median of 110 months (range 12 to 270) with a median continence score of 10/24; this score was confirmed at longer-term follow-up (132 months, range 60 to 276) of 185 patients. The authors found that SNS is an effective treatment in the long term with improvement of validated scores for approximately 60% of patients. However, it should be noted that there is a significant reduction of efficacy over time due to underlying causes.

In a 2020 large retrospective cohort, Desprez et al identified patients who had a sacral nerve modulation implantation procedure more than 10 years earlier for fecal incontinence to assess long-term efficacy. Of the 360 patients (27 males, mean age:  $59 \pm 12$  years) implanted for FI, 162 (45%) had a favorable outcome 10 years post-implantation, 115 (31.9%) failed, and 83 (23.1%) were lost to follow-up. The favorable outcome derived from the time-to-event Kaplan-Meier curve at 10 years was 0.64 (95% CI 0.58-0.69). FI severity scores were significantly better 10 years post-implantation compared to preimplantation ( $7.4 \pm 4.3$  vs  $14.0 \pm 3.2$ ;  $P < 0.0001$ ). During the 10-year follow-up, 233 patients (64.7%)

had a surgical revision and 94 (26.1%) were explanted. A history of surgery for FI and sex (male) were associated with an increased risk of an unfavorable outcome. The authors found that long-term efficacy was maintained in approximately half of the FI patients treated by SNM at least 10 years post-implantation.

A 2022 retrospective cohort study (Picciariello et al) identified 58 patients who met criteria inclusion and had a sacral nerve modulation implantation procedure more than 10 years earlier for FI to determine long term functional outcomes and quality of life. Thirty six out of the 58 patients agreed to take part in a phone interview, while 22 were lost to the follow-up. Nineteen patients had their IPG removed (Group A) while 17 (27%) had the SNM still active after a median follow-up of 13 years (Group B). In the group A, the median baseline St Marks' score was 13 and did not change after the IPG removal. In group B, the median baseline St Marks' score was 14, at last IPG substitution, it was of 7 and at the last follow-up dropped to 4. In the group A, the median SF-12 physical and mental scores did not change significantly while they improved significantly in group B. The authors concluded that while the study focuses on the important issue of the long-lasting duration of SNM only about 1/3 of the patients from those who were among the originally implanted, will benefit from the effectiveness of the SNM for fecal incontinence in the very long-term (more than 10 years).

Several systematic reviews have also been published regarding SNS in the treatment of fecal incontinence. A 2015 Cochrane review (Thaha et al) assessed sacral nerve stimulation (SNS) for fecal incontinence and constipation in adults. Six crossover trials assessed the effects of SNS for severe FI and two parallel group trials were included. In one of the parallel group trials (Tjandra et al, 2008), 53 participants with severe FI in the SNS group experienced fewer episodes of faecal incontinence compared to the control group who received optimal medical therapy (mean difference (MD) -5.20, 95% confidence interval (CI) -9.15 to -1.25 at 3 months; MD -6.30, 95% CI -10.34 to -2.26 at 12 months). Adverse events were reported in a proportion of participants: pain at implant site (6%), seroma (2%) and excessive tingling in the vaginal region (9%). In the other parallel group trial (Thin et al, 2015), 15 participants with FI in the SNS group experienced fewer episodes of FI compared with the percutaneous tibial nerve stimulation (PTNS) group (MD -3.00, 95% CI -6.61 to 0.61 at 3 months; MD -3.20, 95% CI -7.14 to 0.74 at 12 months). Adverse events were reported in three participants: mild ipsilateral leg pain during temporary testing (n = 1); and stimulator-site pain following insertion of neurostimulator (n = 2). The authors found limited evidence from the included trials that suggests SNS can improve continence in a proportion of patients with faecal incontinence and SNS did not improve symptoms in patients with constipation. In addition, adverse events occurred in some patients where these were reported. However, more rigorous high quality randomized trials are needed to allow the effects of SNS for these conditions to be assessed with more certainty.

NICE has also issued guidance on the management of fecal incontinence in 2007 which was last reviewed in 2022 without changes to the recommendations. The guidance states: "A trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate... All individuals should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. People with fecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success."

In 2014, the American College of Gastroenterology (ACG) clinical guideline on the management of benign anorectal disorders, including fecal incontinence, found sacral nerve stimulation should be considered in FI for those who do not respond to conservative therapy (Wald et al, 2014). The 2021 update of these guidelines keep the recommendation for sacral nerve stimulation in patients with fecal

incontinence refractory to medical therapy the same as in the 2014 version (Wald et al, 2021). Additionally, due to a lack of evidence supporting efficacy and the risk of adverse events and complications, the 2021 ACG Panel makes a statement stating that sacral nerve stimulation "cannot be recommended in patients with constipation of any type."

This was followed in 2015 by the American Society of Colon and Rectal Surgeons (ASCRS) released a clinical practice guideline for the treatment of fecal incontinence. They stated that "sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects". This was based on an evidence grade of recommendation: Strong, based on moderate-quality evidence, 1B." In 2016, the ASCRS released an updated clinical practice guideline for the management of constipation. In this guideline, they stated sacral neuromodulation may be an effective treatment for patients with chronic constipation and successful peripheral nerve evaluation test when conservative measures have failed; however, it is not currently approved by the FDA for this condition. This recommendation was graded "Weak" based on moderate quality evidence, 2B.

In 2020, ACOG issued a practice bulletin on fecal incontinence which stated, "Sacral nerve stimulation can be considered as a surgical treatment option for women with fecal incontinence with or without anal sphincter disruption who have failed conservative treatments."

In 2021, the Emergency Care Research Institute (ECRI) Clinical Evidence Assessment that evaluated implantable SNS for treating urinary incontinence (UI). The assessment used data from two systematic reviews, two extensive before-and-after studies, two large case series, and one RCT. Evidence limitations included the risk of bias in the RCT due to lack of outcome assessor blinding, the retrospective design of the case series, and lack of parallel controls in the before-and-after studies. The RCT included in the assessment suggests InterStim works as well as other treatments such as botulinum toxin (Botox®) for decreasing UI. The authors concluded that InterStim is safe and effective in relieving UI and urinary frequency symptoms in most individuals with UI (ECRI, 2012; updated April 2021).

ECRI also performed a Clinical Evidence Assessment on the InterStim II System's (Medtronic plc.) effectiveness in restoring bowel control for individuals with chronic fecal incontinence (FI) in 2021. The evidence assessment consisted of a technology assessment, five RCTs, one systematic review, and two pre/post-treatment studies. Of the five RCTs included, four compared InterStim with sham and optimal medical therapy for individuals with varying disease severity. The technology assessment and systematic review are at risk for bias due to the small sample size, single-center study design, retrospective data, lack of randomization, and blinding. RCTs that compare InterStim with other treatments would be necessary to provide comparative data. However, the assessment concluded that InterStim is safe and effective, appearing to improve continence for up to five years in those individuals with chronic FI.

Lastly, in 2021, ECRI assessed the Axonics rechargeable SNM (Axonics Modulation Technologies, Inc.) for treating UI. The assessment indicated that SNM is generally a safe and effective treatment option for specific individuals with UI; however, the evidence is limited to two small sample sized before-and-after studies. Limitations to the literature include a considerable risk of bias, a small sample size, and a lack of comparison of Axonics to other therapies. Overall, additional studies such as RCTs that report long-term outcomes are necessary to assess the comparative safety and effectiveness of Axonics SNM to other treatments. In the treatment of FI, the authors uncovered evidence indicating SNM is a generally safe and effective treatment option for some individuals with FI. The literature supporting SNM derives from two before and after studies, creating limitations of the evidence such as small sample size, lack of parallel controls, and risk for bias. Overall, RCTs comparing long-term individualized outcomes of Axonics r-SNM with other treatments for FI are necessary to accurately assess Axonics safety and efficacy.

## Applicable Coding

### CPT Codes

<b>0787T</b>	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
<b>64561</b>	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
<b>64581</b>	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
<b>64585</b>	Revision or removal of peripheral neurostimulator electrode array
<b>64590</b>	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
<b>64595</b>	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

### HCPCS Codes

<b>A4290</b>	Sacral nerve stimulation test lead, each
<b>C1767</b>	Generator, neurostimulator (implantable), nonrechargeable
<b>C1778</b>	Lead, neurostimulator (implantable)
<b>L8679</b>	Implantable neurostimulator, pulse generator, any type
<b>L8680</b>	Implantable neurostimulator electrode, each
<b>L8684</b>	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
<b>L8685</b>	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
<b>L8686</b>	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
<b>L8687</b>	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
<b>L8688</b>	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

### **References:**

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