# Sacral Nerve Stimulation for Urinary and Fecal Indications

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➲ Instructions for Use

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## Application

### UnitedHealthcare Commercial
This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

### UnitedHealthcare Individual Exchange
This Medical Policy applies to Individual Exchange benefit plans.

## Coverage Rationale

➲ See Benefit Considerations

**Note**: This policy applies to individuals ≥ 18 years of age.

**Sacral Nerve Stimulation (neurostimulation) screening trial is proven and medically necessary for treating urinary voiding dysfunction when all the following criteria are met:**
- Lower urinary tract symptoms, as indicated by one or more of the following:
  - Overactive bladder symptoms (also known as urgency frequency syndrome)
  - Urge Incontinence
  - Nonobstructive urinary retention (NOUR)
- Bladder capacity of 100 ml or greater
- Urinary voiding dysfunction is not secondary to a neurologic disease origin [e.g., Parkinson's disease, stroke, spinal cord injury, multiple sclerosis (MS)]
- No bladder outlet or mechanical obstruction [e.g., BPH, obstruction caused by cancer (tumor or prior radiation therapy), urethral stricture]
- Symptoms refractory to conservative care (e.g., bladder training, pelvic floor rehabilitation, pharmacological therapy)
- Individual capable of operating sacral nerve stimulating device

**Sacral Nerve Stimulation (neurostimulation) permanent implantation for treating urinary voiding dysfunction is proven and medically necessary when all the following criteria are met:**
- All criteria for Sacral Nerve Stimulation screening trial have been met

- Improvement in reported symptoms of 50% or greater in response to a screening trial of Sacral Nerve Stimulation

**Sacral Nerve Stimulation (neurostimulation) screening trial is proven and medically necessary for treating Fecal Incontinence when all the following criteria are met:**
- Symptoms refractory to conservative care (e.g., bowel training, bulking agents, pelvic floor rehabilitation, pharmacological therapy)
- Individual capable of operating sacral nerve stimulating device
- Fecal Incontinence is not secondary to a neurologic disease origin [e.g., Parkinson's disease, stroke, spinal cord injury, multiple sclerosis (MS)]
- Fecal Incontinence is not secondary to Constipation
- Lack of distorted anatomy (e.g., anorectal malformation, abscess or fistula, rectal surgery)

**Sacral Nerve Stimulation (neurostimulation) permanent implantation for treating Fecal Incontinence is proven and medically necessary when all the following criteria are met:**
- All criteria for Sacral Nerve Stimulation screening trial have been met
- Improvement in reported symptoms of 50% or greater in response to a screening trial of Sacral Nerve Stimulation

**Sacral nerve stimulator replacement or revision is considered medically necessary when the individual has met all the above criteria and the existing device is nonfunctional, and either cannot be repaired or is no longer under warranty.**

**Sacral Nerve Stimulation (neurostimulation) for the treatment of Constipation and Chronic Pelvic Pain is considered unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.**

## Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

## Definitions

**Chronic Pelvic Pain**: Chronic Pelvic Pain (CPP) is defined as: persistent or recurrent episodic pelvic pain associated with symptoms suggesting lower urinary tract, sexual, bowel, or gynecological dysfunction with no proven infection or other obvious pathology (Fall et al., 2010).

**Chronic Urinary Retention**: Chronic Urinary Retention is diagnosed when an individual has: a postvoid residual volume (PVR) ≥ 300 milliliters (mL) that persists for ≥ 6 months and is documented on ≥ 2 separate occasions (Stoffel et al., 2016).

**Constipation**: Constipation is a syndrome that is defined by bowel symptoms (difficult or infrequent passage of stool, hardness of stool, or a feeling of incomplete evacuation) that may occur either in isolation or secondary to another underlying disorder (Bharucha et al., 2013).

**Fecal Incontinence**: Fecal Incontinence (FI) is the involuntary passage of fecal matter through the anus or the inability to control the discharge of bowel contents. Its severity can range from an involuntary passage of flatus to complete evacuation of fecal matter (Shah & Villanueva Herrero, 2022).

**Fowler's Syndrome**: Fowler's Syndrome is characterized by a large bladder capacity, reduced sensation, increased maximal urethral closure pressure, and detrusor underactivity. The functional causes are a result of the pathological changes in the contraction of the periurethral muscles (dysfunctional voiding and detrusor sphincter dyssynergia) or impaired urethral relaxation. Fowler's Syndrome typically occurs in post-menarche young women in the second and third decades of life. Most of the patients reveal a trigger medical event in their history, such as gynecological surgery or other surgical procedures, childbirth, and acute medical conditions (Szymański et al., 2021).

**Sacral Nerve Stimulation (SNS) [Also Known as Sacral Neuromodulation (SNM) or Urologic Nerve Stimulation]**: A small electrode tip is placed near the sacral nerve, the nerve that controls voiding function in the lower spine. An implanted device stimulates the nerve to act as a sort of pacemaker for the bladder, improving urinary function and

reducing or eliminating pain. SNS was originally used to treat urinary symptoms such as overactive bladder, Urge Incontinence, and non-obstructive urinary retention. It is also being explored for interstitial cystitis, neurogenic bladder, dysfunctional elimination syndrome in children, Fecal Incontinence, Constipation, and Chronic Pelvic Pain (Garcia, 2012).

**Urge Incontinence**: Urge Incontinence [Also known as urinary Urge Incontinence (UUI)] is: a type of Urinary Incontinence in adults, which involves sudden compelling urges to void and results in involuntary leakage of urine (Nandy & Ranganathan, 2022).

**Urinary Incontinence**: Urinary Incontinence (UI) is known as the leakage of any volume of urine, which is mostly involuntary (Nandy & Ranganathan 2022).

# Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|---|---|
| 0784T | Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed |
| 0785T | Revision or removal of neurostimulator electrode array, spinal, with integrated neurostimulator |
| 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 |
| 64561 | Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed |
| 64581 | Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) |
| 64585 | Revision or removal of peripheral neurostimulator electrode array |
| 64590 | Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver |
| 64595 | Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array |



| HCPCS Code | Description |
|---|---|
| L8679 | Implantable neurostimulator, pulse generator, any type |
| L8680 | Implantable neurostimulator electrode, each |
| L8682 | Implantable neurostimulator radiofrequency receiver |
| L8685 | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension |
| L8686 | Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension |
| L8687 | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension |
| L8688 | Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension |

| Diagnosis Code | Description |
|---|---|
| **Urinary Indications** | |
| N32.81 | Overactive bladder |
| N32.9 | Bladder disorder, unspecified |
| N39.3 | Stress incontinence (female) (male) |
| N39.41 | Urge incontinence |
| N39.42 | Incontinence without sensory awareness |
| N39.46 | Mixed incontinence |

| Diagnosis Code | Description |
|---|---|
| **Urinary Indications** | |
| N39.490 | Overflow incontinence |
| N39.498 | Other specified urinary incontinence |
| R30.0 | Dysuria |
| R30.1 | Vesical tenesmus |
| R30.9 | Painful micturition, unspecified |
| R32 | Unspecified urinary incontinence |
| R33.0 | Drug induced retention of urine |
| R33.8 | Other retention of urine |
| R33.9 | Retention of urine, unspecified |
| R35.0 | Frequency of micturition |
| R35.1 | Nocturia |
| R35.81 | Nocturnal polyuria |
| R35.89 | Other polyuria |
| R39.11 | Hesitancy of micturition |
| R39.12 | Poor urinary stream |
| R39.13 | Splitting of urinary stream |
| R39.14 | Feeling of incomplete bladder emptying |
| R39.15 | Urgency of urination |
| R39.16 | Straining to void |
| R39.191 | Need to immediately re-void |
| R39.192 | Position dependent micturition |
| R39.198 | Other difficulties with micturition |
| R39.81 | Functional urinary incontinence |
| R39.89 | Other symptoms and signs involving the genitourinary system |
| R39.9 | Unspecified symptoms and signs involving the genitourinary system |
| **Fecal Indications** | |
| R15.0 | Incomplete defecation |
| R15.1 | Fecal smearing |
| R15.2 | Fecal urgency |
| R15.9 | Full incontinence of feces |

# Description of Services

Sacral Nerve Stimulation (SNS), also referred to as sacral neuromodulation (SNM), is a safe, effective, and minimally invasive therapy to treat Urinary Incontinence, urinary retention, urgency, frequency, and Fecal Incontinence. Research suggests that placement of the SNM lead in the S3 region will cause stimulation of afferent fibers from the anal sphincter, rectum, and pelvic floor. SNM inhibits the guarding reflex and induces voiding in individuals with urinary retention. SNM appears to stimulate the relaxation of pelvic floor muscles and the urethra, which helps initiate micturition for individuals with impaired bladder pressure, retention, and incomplete emptying (Feloney et al., 2022).

Individuals first undergo a trial of 3 to 7 days to determine eligibility for a neurostimulator. Individuals who have had a successful test stimulation, usually defined as improvement in reported symptoms of 50% or greater in response to a screening trial of SNS, may undergo implantation of a permanent neurostimulator. Permanent SNS implantation is performed under general anesthesia. Briefly, a midline sacral incision is made down to the level of the lumbodorsal fascia, which is opened about 1.5 centimeters from the midline. An insulated needle is placed into the appropriate foramen, and the motor responses are evaluated until the appropriate foramen is located. The connecting lead and neurostimulator are then connected. The incision is closed in layers usually, without drains. A confirmatory radiograph is obtained before discharge (Das et al., 2000).

# Clinical Evidence

## Urinary Indications

In 2025, Hayes published an emergent technology report on the Sacral Neuromodulation (SNM) System for urinary urge incontinence. The neurostimulator is a miniaturized implantable sacral nerve stimulation (SNS) device with an integrated receiver and electrode array that is powered wirelessly. The Sacral Neuromodulation Systems is the first miniaturized integrated receiver/electrode array SNS system for treatment of urgency urinary incontinence (UUI) approved by the U.S. Food and Drug Administration (FDA). The review found that the best available published evidence is limited to a first-in-human study evaluating the feasibility and safety of brief implantation of the device in 5 participants with overactive bladder (OAB) and no conclusions may be drawn regarding the efficacy and long-term safety of the system for the treatment of UUI.

Through a 2025 systematic review, Amundsen et al. aimed to indirectly compare the efficacy and safety of the SNM and implantable tibial neuromodulation (iTNM) for treating OAB and neuromodulation. The primary efficacy measured was a ≥ 50% reduction in UUI episodes, urinary frequency, and/or OAB symptoms. The safety measures included the rate of the device-related adverse events (AEs). The study included a total of 1416 individuals who were treated with SNM and 350 individuals treated with iTNM. Weighted averages showed that the UUI responder rate was similar for both SNM and iTNM (71.8% and 71.3%, in that order). Correspondingly, the weighted averages of OAB responder rates were 73.9% for SNM and 79.4% for iTNM. Comparable rates of device-related AEs were also observed. The authors concluded that there was similar efficacy and safety of SNM and iTNM for treating OAB and UUI, including UUI and OAB symptom response rates, reduction in UUI episodes, significant advances in quality of life (QoL), and low rates of procedure and device related AEs. Markedly, this comparable efficacy was seen without the use of a trial phase of neuromodulation in the iTNM studies versus SNM studies. The limitations of the study included a moderate risk of bias, retrospective study design and single-center nature of several of the studies (Amundsen et al. 2018; and Siegel et al. 2018 are included in this review).

In 2025, Yu et al. conducted a network meta-analysis to assess the available evidence of noninvasive or minimally invasive neuromodulation therapies in improving urodynamic outcomes, voiding diaries, and QoL in those with neurogenic lower urinary tract dysfunction (NLUTD) after a spinal cord injury (SCI). The included study selection was randomized controlled trials (RCTs) assessing the effects of conventional treatment (CT), and CT combined with sham stimulation transcranial magnetic stimulation (TMS), sacral neve magnetic stimulation (SNMS), TMS+SNMS, sacral pulsed electromagnetic field therapy (SPEMFT), sacral transcutaneous electrical nerve stimulation (STENS), sacral dermatomal transcutaneous electrical nerve stimulation, bladder & STENS, transcutaneous tibial nerve stimulation (TTNS), transcutaneous electrical acupoint stimulation, pelvic floor electrical stimulation, or pelvic floor biofeedback therapy on postvoid residual volume (PVR), maximum cystometric capacity (MCC), number of voids per 24 hours (V24), mean urine volume per micturition, (MUV), maximum urinary flow rate (Qmax), maximum detrusor pressure (MDP), maximum voiding volume, number of leakages per 24 hours (L24), lower urinary tract symptoms score, and SCI-quality of life (SCI-QoL) score in those with NLUTD after SCI. The data synthesis resulted in 2884 participants being included in the analysis. The results demonstrated that CT+TMS was able to remarkably decrease PVR and increase MUV. CT+SNMS ranked high in improving V24 and reducing L24; CT+TMS+SNMS maximized the decrease of SCI-QoL scores and ranked second in both reducing PVR and improving MCC; CT+SPEMFT had a significant advantage in improving MCC and increasing Qmax. Improvement in MDP was highly ranked by CT+TTNS. The authors concluded that CT combined with magnetic stimulation therapy provided more benefits than its combination with electrical stimulation. TMS +SNMS was a promising noninvasive neuromodulation technique for the management of NLUTD after SCI. The limitations of the study included the lack of high-quality trials, and most of the RCTs included were small sample sizes, along with a lack in data which limited the strength of conclusions. Furthermore, safety and efficacy could not be evaluated due to few studies reporting AEs. It was determined that high-quality RCTs should be conducted in the future to validate these findings.

Coolen et al. 2023 sought to determine the success rate of the tined lead test phase for individuals with nonobstructive urinary retention (NOUR), determine predictive factors of a successful test phase for those with NOUR, and determine the long-term treatment efficacy and satisfaction for individuals with NOUR. The results of the multicenter study included 215 consecutive participants who experienced a tined lead test phase for the treatment of NOUR. The success rate in women was significantly higher than in men, respectively 62% (83/133) and 22% (18/82, $p < 0.001$). In women, age per ten years [odds ratio (OR) 0.74, 95% CI: 0.59-0.93] and a history of psychiatric illness (OR 3.92, 95% CI: 1.51-10.2), including posttraumatic stress disorder (PTSD), meaningfully predicted first stage SNM success. In men, age per ten years (OR 0.43, 95% CI: 0.25-0.72) and prior transurethral resection of the prostate and/or bladder neck incision (OR 7.71, 95% CI: 1.43-41.5) were significant predictors of success. Conversely, failure to void during a urodynamic study (for women, OR 0.79, 95% CI: 0.35-1.78; for men, OR 3.06, 95% CI: 0.83-11.3) was not predictive of success. Of the individuals with a successful first stage, 75% (76/101) replied to the questionnaire at a median follow-up of three years. Of these, 87% (66/76) continued to use their SNM system, and 92% (70/76) would advocate for SNM to other individuals. The limitations

of the study included the retrospective nature of the study. The authors concluded that a history of psychiatric illness, including PTSD, in women with NOUR enhanced the odds of first stage SNM success 3.92 times. A prior transurethral resection of the prostate and/or bladder neck incision in men increased the odds of success 7.71 times. In addition, a ten-year age increase was correlated with an OR of 0.43 in men and 0.74 in women, implying 2.3- and 1.3-times decreased odds of success, respectively (included in the 2024 updated Hayes report).

In 2023, Huang et al. investigated the comparative efficacy of neuromodulation technologies for overactive bladder (OAB) syndrome in adults. The outcomes measured were voiding diary, OAB related QoL, and positive response rate. The investigation uncovered 21 RCTs including 1433 participants and the trials were utilized for the meta-analysis where five of six neuromodulation technologies, including peripheral tibial nerve stimulation (PTNS), TTNS, vaginal electrical stimulation (VES), SNM, and parasacral stimulation (PS) were related to higher efficacy than the placebo. According to the ranking probability, SNM was the most efficacious therapy for improving OAB related QoL, urinary episodes, and urinary frequency. For urgency incontinence episodes and the number of pads, PTNS and TTNS were the most efficacious modalities, respectively. The authors concluded that neuromodulation technologies including PTNS, TTNS, VES, SNM and PS may be effective and safe solutions for OAB syndrome in adults. PTNS and TTNS were found to be the most effective for reducing urgency incontinence episodes and the number of pads, respectively. Studies in the future should focus on the quality of the study design and report on individuals who may benefit the most from neuromodulation, and the long-term effect, cost-effectiveness, and satisfaction of neuromodulation effectiveness.

A 2022 Hayes Health Technology Assessment was conducted to evaluate the utilization of SNS in treating NOUR. The assessment consisted of evidence from six studies, including one RCT, one pretest-post-test study, one repeated measures study, and three case series with follow-ups ranging from 10 months to 8 years. The evidence suggests that SNS improves outcomes for individuals who have NOUR; however, it cautions individuals who have chronic refractory NOUR as they are frequently not candidates for SNS therapy due to inadequate response during initial testing. Overall, the evidence evaluated in this assessment described SNS as a reasonable treatment option for individuals with intractable NOUR who are not responding to standard or alternative therapies and who meet the criteria for permanent implantation. In the 2025 Hayes Health Technology Assessment update, there are 4 newly published studies that may meet the inclusion criteria set out in the report published in 2022. The newly published studies include new evidence regarding efficacy, patient selection criteria, and safety.

In 2022, Liu et al. conducted a systematic review and network meta-analysis using RCTs to compare the efficacy and safety of interventions for treating idiopathic OAB. The interventions compared were antimuscarinics, mirabegron, OnabotulinumtoxinA (BTX), SNM, and PTNS. Included in the analysis were 32,507 individuals, where it was found that overall, antimuscarinics, mirabegron, BTX, SNM, and PTNS were more efficacious than placebo with SNM demonstrating the best effect for reducing micturition frequency, urgency episodes, and UUI episodes. For reductions in UI episodes/day, BTX was the best intervention (100 and ≥ 50%). PTNS reduced most UI episodes, and antimuscarinics, mirabegron, and PTNS have similar efficacy for reducing micturition frequency, UI episodes, and UUI episodes. The limitations of the study included the short-term efficacy at the 12-week follow-up, with a lack of comparison of long-term effectiveness. Additionally, the placebo differed in their mode of administration depending on the treatment intervention. The authors concluded that although all interventions were efficacious for managing adult OAB syndrome compared to placebo, SNM and BTX were the most efficient treatments for OAB.

A Hayes Health Technology Assessment was conducted to analyze PTNS for treating symptomatic nLUTD and reports SNS as a proper clinical alternative to PTNS. The assessment describes PTNS and SNS as third-line treatments for individuals refractory to behavioral or pharmacologic therapy. Overall, the literature evaluated in this assessment designated PTNS as a minimally invasive alternative to SNS; however, studies comparing the two technologies are lacking (Hayes, 2019; updated 2022).

Tilborghs & Wachter (2022) conducted a systematic review of the literature on SNM for the treatment of OAB. The comprehensive literature search for the collection of articles related to SNM for OAB was conducted utilizing the following databases: PubMed/MEDLINE, Cochrane, and Scopus. Studies included those with at least 50 individuals who received SNM therapy for OAB and had a follow-up of at least 12 months to evaluate the safety and efficacy of SNM. The literature review uncovered no life-threatening or major irreversible complications. According to the authors, SNM proved to be a safe and effective therapy for OAB for the short, medium, and long term without precluding other treatment options.

A 2021 Hayes Evolving Evidence Reviewed a Sacral Neuromodulation device for managing urinary dysfunction investigated full-text studies, systematic reviews, clinical practice guidelines, and position statement's support of the technology. The review of clinical studies suggested minimal support for using SNM for treating lower urinary tract dysfunction and no support from systematic reviews. The evolving evidence review found strong support for using SNM in managing urinary dysfunction in full-text clinical practice guidelines and position statements. Based on the 2023 updated

evolving evidence review, one newly published clinical study was included in the report. The literature evaluation indicates new evidence regarding efficacy and no further evidence regarding safety or longer-term follow-up. In 2024, one newly published clinical study that may meet the inclusion criteria set out in the 2021 report was identified. The review of literature indicates that new evidence regarding efficacy has become available.

A Hayes Health Technology Assessment compared the effectiveness of PTNS to BTX and SNS for treating symptomatic non-neurogenic OAB. The assessment describes SNS, TTNS, and transvaginal pelvic floor electrostimulation as alternative treatments for OAB. Additionally, the evidence shows that treatment options such as BTX or neuromodulation, including SNS or PTNS, are proper treatment options when an individual has failed behavioral and pharmacologic therapies. Overall, there is a necessity for further research into the use of PTNS for maintenance therapy of OAB syndrome. Well-designed comparative or controlled studies on the efficacy and safety of maintenance therapy past the initial treatment course with PTNS are lacking (Hayes, 2018; updated 2021). In the 2022 update, five newly published studies were included in the assessment. Evaluation of the literature indicates new evidence regarding efficacy and safety. There is no further evidence regarding patient selection, longer-term follow-up, and no new applications of the technology.

In the 2019 Hayes health technology assessment, updated in 2022, PTNS was evaluated for treating symptomatic nLUTD. The outcome of the assessment found that although the results of this small body of evidence suggest that PTNS is safe and may provide subjective and objective improvement over the short term in nLUTD secondary to MS, PD, or other neurologic conditions, questions remain about comparative effectiveness and safety relative to other treatments for nLUTD, the durability of improvement and requirements for maintenance therapy, and which patients may derive benefits.

A neuromodulatory device was the subject of an ECRI Clinical Evidence Assessment that evaluated implantable SNS for treating 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 the lack of outcome assessor blinding, the retrospective design of the case series, and the lack of parallel controls in the before-and-after studies. The RCT included in the assessment suggests 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).

An ECRI Clinical Evidence Assessment evaluated rechargeable SNM 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 the therapy to other therapies. Overall, additional studies such as RCTs that report long-term outcomes are necessary to assess the comparative safety and effectiveness of SNM to other treatments (ECRI, 2019; updated 2021).

Elterman et al. (2021) directed a prospective, multicenter, international RCT to explore the effects of the SNM's three different amplitude settings in female subjects with OAB symptoms such as urinary urge incontinence (UUI). The impact of sub-sensory amplitude settings on OAB symptoms was evaluated using voiding diaries at six and 12 weeks during SNM therapy. To be included in the trial, the participant must have a primary diagnosis of UUI, be female, 18 years of age or older, be a candidate for SNS placement and be willing to maintain a current regimen of OAB medication. Exclusion criteria prohibited individuals with neurological conditions, uncontrolled diabetes, urinary tract infection (UTI), stress incontinence, or those who received treatment with Botox in the past nine months. Subjects who completed enrollment/baseline visits, lead implant, therapy evaluation, and neurostimulator device implant were randomized in a 1:1 ratio to one of three amplitude settings [50% of sensory threshold (ST), 80% of ST, and ST]. Individuals logged in the voiding diaries at baseline, therapy evaluation, and six and 12-week follow-up visits. QoL was assessed using the validated international consultation on incontinence modular questionnaire—OAB symptoms quality of life (ICIQ-OABqol) at baseline and 12 weeks. Subjects' feeling of improvement was evaluated using the patient global impression of improvement (PGI-I) questionnaire at six and 12-week follow-up visits. Successful test stimulation was defined as ≥ 50% improvement in UI or urinary frequency voiding symptoms or a return to normal voiding of fewer than eight voids per day for subjects with urinary frequency. Successful test stimulation was demonstrated in 48 individuals; 46 were implanted with a neurostimulator device, and 43 completed the 12-week follow-up visit. The UI outcomes were as follows; the change from baseline to 12 weeks was −3.0 UI episodes/day (95% CI: −4.4 to −1.7) for the 50% of the ST group, −2.9 UI episodes/day (95% CI: −4.7 to −1.2) for 80% of ST group, and −3.6 UI episodes/day (95% CI: −5.2 to −1.9) for the ST group. Post-hoc analyses indicated a significant decrease in UI episodes at all three amplitude settings at six and 12 weeks compared to baseline (all $p < .004$). Regarding QoL, the PGI-I questionnaire showed that subjects across all three randomized groups reported improvement in their bladder condition at 12 weeks compared to before treatment with SNM therapy (PGI-I questionnaire responses 82.4%, 92.3%, and 92.3% for the 50%, 80%, and ST groups, respectively). According to the researchers, this study proved that individuals with sub-sensory amplitude settings at 50%, 80%, and ST

experienced reduced UI episodes. The authors conclude that the outcomes of the trial show possible advancements in the post-implantation phase of InterStim therapy with improved comfort for individuals suffering from OAB symptoms.

In a systematic review and meta-analysis by van Ophoven et al. (2021) on SNM in individuals with nLUTD, NOUR, or a combination of both, authors searched the literature between 1998 and March 2020 using the Preferred Reporting Items for systematic reviews and Meta-Analyses (PRISMA) statement. The systematic literature review yielded 47 studies; 21 (887 individuals) were included in the meta-analysis of test SNM, and 24 (428 individuals) in the meta-analysis of permanent SNM. The level of evidence was assessed using the Oxford Centre for Evidence-Based Medicine and ranged from 3 to 4. Individuals with nLUTD who received SNM were divided into three subgroups: neurogenic detrusor overactivity (nDO), neurogenic NOUR, or a combination of both, resulting in test SNM success rates for nDO 61%, 52% for neurogenic NOUR, and 69% for a combination of both. Meta-analyses were conducted to generate pooled estimates for test and permanent SNM success rates. Test success rates varied significantly depending on neurogenic conditions; however, the pooled success rate of SNM test stimulation was 66.2%. The meta-analysis of permanent SNM resulted in a pooled success rate of 84.2%. The pooled success rates for test and permanent SNM were 64.2% and 82.9%, respectively. Adverse events (AEs) were reported in less than 25% of 494 individuals, with the most common being loss of effectiveness (4.7%), infection (3.6%), pain at the implant site (3.2%), and lead migration (3.2%). Limitations include the risk of bias; in some studies, there were small sample sizes, retrospective case series included, heterogeneous populations, lack of disease classification, and variations in terms of outcome parameters along with techniques. The systematic reviews and meta-analysis support the high overall success rates and the benefits of permanent SNM for various nLUTDs.

Lo et al. (2020) compared the efficacy of BTX, SNM, and PTNS as a third-line treatment for managing OAB symptoms in adults through a systematic review and network meta-analysis. Utilizing the PRISMA flow diagram, the search was conducted from January 1995 to September 2019, resulting in 20 articles. The studies all met the qualitative inclusion criteria, including 17 RCTs (3,038 individuals) that compared any dose of BTX, SNM, and PTNS with each other or a placebo for managing adult OAB. The results were reported as an average number of episodes at baseline for each trial outcome. The efficacy of treatments for urinary frequency from nine studies showed a more significant reduction in micturition per day for those treated with SNM compared with the placebo PTNS and BTX. To compare the efficacy of the three modalities on the number of incontinent episodes per day at 12 weeks of follow-up, seven studies were used revealing that all three modalities were more efficacious than the placebo. However, the network meta-analysis showed SNM demonstrated a more significant reduction in the total number of incontinences per day compared to placebo, PTNS, and BTX. From 10 studies, the treatment effects on UTIs were evaluated, revealing that BTX was associated with a higher incidence of UTIs compared with placebo SNM and PTNS. In 11 studies, authors found that the impact of treatments with BTX on post-management urine retention was associated with a higher occurrence of post-treatment urine retention needing catheterization compared to placebo, SNM, and PTNS. Limitations included the lack of studies using standardized questionnaires and parameters to assess the long-term effectiveness of the three treatment options. Overall, this systematic review and meta-analysis showed that all three treatments were more efficacious in managing adult OAB syndrome than the placebo. BTX resulted in more complications, such as UTI and urine retention. At the 12-week follow-up, SNM resulted in the most significant reduction in UI episodes and voiding frequency compared with BTX and PTNS.

Yang et al. (2020) systematically reviewed the literature on individuals with refractory OAB who chose SNM therapy after failed BTX treatment and performed a meta-analysis of the collected data. To assess the quality of the literature, the authors employed the Newcastle-Ottawa Scale (NOS) along with two independent reviewers who screened the studies and extracted data. The exploration resulted in seven studies including 319 individuals who met the inclusion criteria. The authors discovered a 58.5% success rate in individuals with refractory OAB utilizing SNM therapy after failed BTX therapy and no significant difference between individuals with refractory OAB who chose SNM as a first choice [RR = 0.96, 95% CI (0.72–1.26), p = 0.735]. Limitations to the study include limited pertinent research, small research samples, scarcity of RCTs, homogeneity, sensitivity, and linguistic constraints. The authors concluded that in treating OAB, SNM therapy has long-term and stable healing effects with a significant overall success rate for individuals with OAB who chose SNM after failing BTX or as a first-choice therapy.

In a multicenter, open-labeled, randomized extension trial by Amundsen et al. (2018), the authors compared two-year outcomes of SNM to BTX for individuals with refractory UUI. The trial began in February 2012 and ended in July 2016. In nine US medical centers, 386 women with ≥ six urinary urge incontinence episodes (UUIE) were assessed. Individuals were randomized to SNM (n = 194) or BTX 200 U (n = 192) and were followed to determine AEs. The trial participants were considered clinical responders (CR) to treatment if they demonstrated ≥ 50% reduction in UUIEs after placement of SNM or after one month of BTX treatment. Reprogramming was allowed during the two years for SNM; after six months, two more BTX injections were permitted. The primary outcome was the change in mean daily UUIE over the two years, and secondary outcomes were results of no UUIE, ≥ 75%, and ≥ 50% UUI reduction. The Overactive Bladder Questionnaire Short Form, Urinary Distress Inventory short form, Incontinence Impact Questionnaire, Patient Global

Impression of Improvement, Over-active Bladder Satisfaction of Treatment Questionnaire, and AEs were also utilized to assess outcomes. Over the two years, 58% of the SNM cohort required reprogramming, and 17% required three or more reprogramming. Due to decreased efficacy, the SNM revision rate was 3% at the two-year interval. No difference in decreased mean UUIE for both groups over two years (-3.88 vs. -3.50 episodes/d; mean difference = 0.38; 95% CI = -0.14–0.89; p = 0.2) was reported. The BTX group was more likely to experience complete resolution of UUI at the six-month mark (treatment difference = -18%; 95% CI = -29-6; p < 0.0001) and ≥ 75% reduction, treatment difference = -20%; 95% CI = -31- –8; p = 0.001). The differences between the groups decreased over time, with comparable rates of complete resolution (5% each) and 75% reduction (22% for BTX and 21% for SNM) at the two-year mark. Higher treatment satisfaction and treatment endorsement were demonstrated in the BTX group (treatment satisfaction mean difference = -9.1, 95% CI = -14.4, -3.9; p < 0.001) (treatment endorsement mean difference = -12.2, 95% CI = -17.7 - -6.6; p < 0.001) according to OAB-SATq subscales. AE data was available for 328 out of 369 participants, with only UTI rates being clinically different between groups, as the BTX group experienced more UTIs. The authors found no significant difference in symptoms specific to QoL measures, global improvement assessment, or AE subscales. The trial results demonstrated how both treatments evaluated had continued UUI improvement over two years, with reductions in average daily UUIE (Included in the 2012 ECRI report, the Tilborghs & Wachter systematic review from 2022, the 2022 Liu systematic review and meta-analysis, the 2020 systematic review and meta-analysis by Lo et al. and the 2018 systematic review by Tutolo et al.).

## Fecal Incontinence

In 2024, Marinello et al. assessed the impact of SNM on low anterior resection syndrome (LARS) symptoms as measured by validated scores and bowel diaries through a randomized, double-blind, 2-phased, controlled, multicenter crossover trial (NCT02517853). To conduct the trial, participants with major LARS 12 months after transit reconstruction after rectal resection who had failed conservative treatments underwent an advanced test phase by stimulation for 3 weeks and received the pulse generator implant if a 50% reduction in lower anterior resection syndrome score was achieved. The participants were entered into the randomized phase in which the generator was left active or inactive for 4 weeks. After a 2-week washout, the sequence was changed. Proceeding with the crossover, all generators were left activated. The main outcome assessed was lower anterior resection syndrome score reduction with secondary outcomes including continence and bowel symptoms. The results of the trial after testing showed 35 of 46 participants (78%) had a 50% or greater reduction in LARS score. During the crossover phase, all participants showed a reduction in scores and improved symptoms, with better performance if the generator was active. At 6- and 12-month follow-up, the mean reduction in LARS score was –6.2 (95% CI –8.97 to –3.43; p < 0.001) and –6.97 (95% CI –9.74 to –4.2; p < 0.001), with St. Mark's continence score –7.57 (95% CI –9.19 to –5.95, p < 0.001) and –8.29 (95% CI –9.91 to –6.66; p < 0.001). Urgency, bowel emptiness sensation, and clustering episodes decreased in association with quality-of-life improvement at 6- and 12-month follow-up. The limitations of the trial consist of a possible carryover effect in the sham stimulation sequence, and the decrease in LARS score with neuromodulation was underestimated because of an unspecified measuring instrument.

Through a systematic review, Eggers et al. 2025 aimed to determine the long-term efficacy of SNS for treating fecal incontinence. The comprehensive search of literature resulted in identifying 3326 publications, and 36 studies containing 3770 subjects were included. All studies had a serious risk of bias. Success was variably defined by each publication and ranged from 59.4% to 87.5% for per-protocol analyses and 20.9% to 87.5% for intention-to-treat analyses. All studies reporting bowel diary data, St Mark's scores, and Cleveland Clinic Incontinence Scores indicated significant improvement with SNS treatment in the long term. Studies that evaluated quality-of-life outcomes also all showed improvements in QoL as measured by the Fecal Incontinence Quality of Life Scale. The aggregate revision rate was 35.2%, and the explanation rate was 19.7%. The authors concluded that the improvements in objective and subjective outcomes at ≥ 36 months support using SNS for the long-term treatment of FI. Interpretation of these data is limited by a lack of comparative trials and heterogeneity of the included studies.

An ECRI Clinical Evidence Assessment on a SNM System for Restoring Bowel Control in Patients with Chronic Fecal Incontinence concludes that SNM is safe and appears to improve continence for up to 10 years for most individuals with chronic FI. The clinical evidence assessment is based on one systematic review and four before and after treatment studies. The comparative studies in the systematic review assessed too few individuals and reported too few events per comparison and outcome to allow for conclusions (ECRI, 2020; updated 2022).

The 2021 ECRI Clinical Evidence Assessment evaluated a rechargeable SNM system for treating FI. The assessment 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 r-SNM with other treatments for FI are necessary to assess safety and efficacy accurately.

Ram et al. (2020) conducted a systematic review and meta-analysis to evaluate the efficacy of SNM in treating LARS.

During the study screening, the articles were assessed using the New-castle Ottawa Score. The primary outcome measure was the number of individuals in each group with successful treatment. Out of 434 publications specific to the efficacy of SNM for the treatment of LARS discovered, 13 studies were included in the final analysis. All sacral nerve implantations were achieved in two stages, beginning with an initial temporary peripheral nerve evaluation (PNE) before implantation, resulting in 114 individuals receiving PNE test stimulation. Individuals achieved a successful decrease in FI in 87/114 (76.3%) subjects who underwent PNE test stimulation. Additionally, improvements in anal continence were seen in several clinical and functional parameters demonstrated by the following results: Wexner Score 10.78 points (95% CI 8.55-13.02, $p < 0.0001$), manometric maximum resting pressure mean improvement of 6.37 mm/Hg (95% CI 2.67-10.07, $p = 0.0007$), maximum squeeze pressure mean improvement of 17.99 mm/Hg (95% CI 17.42-18.56, $p < 0.0001$), and maximum tolerated volume mean improvement of 22.74 ml (95% CI 10.65-34.83, $p = 0.0002$). The overall success rate excluding study heterogeneity resulted in 83.30% (95% CI 71.33-95.26%, $p < 0.0001$). Significant advances were also demonstrated in the quality-of-life questionnaires, although the study included a small group of individuals. Limitations include retrospective studies, bias, and lack of control group. The authors concluded that improvements in symptoms and QoL demonstrate a clear benefit of SNM for individuals suffering from FI following low anterior resection. Furthermore, the authors determined SNM is a valuable therapeutic option for refractory FI following rectal resection.

Tan et al. (2020) conducted a systematic review and meta-analysis to quantify placebo effects and responses following sham electrical nerve stimulation for individuals with FI and constipation. The literature search was performed from inception until April 2017 through Ovid MEDLINE, PubMed, EMBASE, and Cochrane databases. Excluded from the review were any pediatric individuals and non-sham-controlled trials. After meeting inclusion and exclusion criteria, ten randomized sham-controlled trials were utilized to investigate the effect of lower gastrointestinal electrical nerve stimulation for treating FI and constipation. The results of the sham stimulation showed improvements in FI episodes by 13 episodes a week (95% CI -2.53 to -0.01, $p = 0.05$), fecal urgency improved by 1.5 episodes a week (CI −3.32 to 0.25, $p = 0.09$), and Cleveland Clinic Severity scores by 2.2 points (CI 1.01 to 3.36, $p = 0.0003$). Improved symptoms of constipation were also seen with the sham stimulation consisting of improved stool frequency (1.3 episodes per week, CI 1.16 to 1.42, $p < 0.00001$), Wexner Constipation scores (5.0 points, CI −7.45 to −2.54 $p < 0.0001$), and Gastrointestinal QoL scores (7.9 points, CI −0.46 to 16.18, $p = 0.06$). The authors conclude that sham stimulation is associated with clinical and statistically meaningful improvements in symptoms of incontinence and constipation.

## Chronic Pelvic Pain

There is insufficient evidence to support SNS via neuromodulation for treating chronic pelvic pain (CPP). Additional high-quality studies are required to demonstrate clinical efficacy and utility and compare this technology to other treatments.

In a 2024 systematic review authors Gish et al. sought to characterize the use and efficacy of neuromodulation techniques for treating CPP syndromes. The literature search resulted in the inclusion of 50 studies, three of which were RCTs, and the remaining were prospective and retrospective case series. The range of pelvic pain conditions treated included interstitial cystitis, peripheral neuralgia, pudendal neuralgia, gastrointestinal pain, urogenital pain, sacroiliac joint pain, and visceral CPP. The authors reported on outcomes encompassing pain, functionality, psychosocial improvement, and medication reduction. The authors concluded that neuromodulation is a developing treatment for numerous chronic pain syndromes. Peripheral nerve stimulation was the least studied form of stimulation. Posterior tibial nerve stimulation offers short-term benefits, but long-term results are difficult. SNS is recognized for use in functional bladder syndromes and appears to propose pain improvement in these individuals as well. Dorsal root ganglion stimulation and SCS have been used for a variety of conditions with promising results. Further studies of homogeneous populations are required before strong recommendations can be made at this time, although pooled analysis may also be impactful.

In the 2023 systematic review and meta-analysis, Greig et al, assessed the outcomes of SNM for treating CPP. The primary results measured were numerical change in pain score, QoL assessment, change in medication use, and all-time complications of SNM. Out of 26 articles, 853 individuals were evaluated. There was a 64.35% successful implantation rate after the test phase. Improvement in pain was reported in 13 studies, with three reporting no significant change. On a 10-point scale, there was a -4.64 [95% confidence interval (CI) = -5.32 to -3.95, $p < 0.00001$] throughout 20 studies which were quantitatively synthesized, and the effects were maintained at the long-term follow-up. All studies reported improved QoL, with 189 complications reported in 1555 individuals. The studies were case series with a risk of bias ranging from low to high risk, from selection bias and loss to follow-up. The authors concluded that SMN is reasonable and effective for treating CPP and significantly reduces pain while increasing QoL with immediate to long-term effects. The study limitations include a lack of a control arm, a small sample size, wide ranges in follow-up time, and a loss of follow-up of individuals with unsuccessful SNM. Studies with a higher level of evidence, including randomized controlled prospective trials with long-term follow-up, which compares SNM with other neuromodulation modalities and CTs, are necessary for conclusive evidence of effectiveness and to make robust clinical recommendations.

Hernández-Hernández et al. (2021) analyzed the records of 105 individuals to determine the long-term outcomes of SNS

in both idiopathic and neurogenic pelvic floor disorders. The authors evaluated efficacy using the Global Response Assessment (range, 0%-100%) and, depending on the clinical indication, used the International Consultation on Incontinence Questionnaire-short form, number of catheterizations or pads a day, and the numerical pain scale. The authors evaluated safety by analyzing complications, reinterventions, and explants; QoL was assessed through phone interviews. The clinical indications were OAB (36 individuals), urinary retention (37 individuals), bladder pain syndrome/interstitial cystitis (BPS/IC) (19 individuals), FI (8 individuals), and double incontinence (DI) (6 individuals). According to the clinical indication, the implant rates were as follows: OAB, 55.6%; urinary retention, 56.8%; BPS/IC, 63.15%; FI, 87.5%; and DI, 66.7%. Results after observing clinical and/or statistically significant improvements in all efficacy variables were as follows: In 34% of individuals, loss of therapeutic effect at 75-month follow-up; in 39% (25 individuals), device-related pain appeared; for 20 of those participants the pain was resolved by reprogramming, and five individuals required removal. The QoL results showed a high level of satisfaction, with more than 90% of individuals stating they would recommend SNS. The authors concluded that SNS offers an alternative for individuals with refractory pelvic floor dysfunction and pain, possessing a favorable profile and providing long-lasting improvements in symptoms and QoL. However, there was a loss of effect, particularly within the first two years, with SNS becoming ineffective in 20% of individuals. Additionally, limitations of the study include small sample size, retrospective nature of the study, and risk of bias (Included in the 2023 systematic review and meta-analysis by Greig et al.).

In 2019, Mahran and colleagues conducted a systematic review and meta-analysis of the literature on the use of SNM to improve CPP symptoms. Overall, fourteen studies were included in the analysis. The primary outcome measure was an improvement in the Visual Analog Scale (VAS) for individuals with CPP compared to different subgroups. Secondary outcome measures compared the effectiveness of SNM in the subgroups based on the SNM approach and etiology of CPP. The authors utilized seven studies, which included 105 individuals with CPP and pure BPS/IC etiology, then compared them with 34 individuals with CPP due to other etiologies. The results demonstrated significantly more improvement in pain scores in the non- BPS/IC group (WMD = −5.72, CI 95% = −6.18 to −5.27) than in the BPS/IC group (WMD = −4.13, CI 95% = −5.36 to −2.90). Seven studies showed significant improvement in urinary frequency (WMD = −8.72, 95% CI = −10.85 to −6.59 $p < 0.001$). Five studies revealed significant overall improvement in urgency (WMD = −1.2, 95% CI = −1.9, to – $p < 0.001$), nocturia (WMD = −2.31, 95% CI = −3.81 to −0.81 $p = 0.003$), and voided volume (WMD = 109.61, 95% CI = 57.79–161.43, $p < 0.001$). The authors concluded that SNM is a promising treatment option for refractory CPP with better effects in treating individuals with etiologies other than BPS/IC. Added higher-quality randomized prospective studies are necessary to compare SNM to other modalities for treating CPP.

Tutolo et al. (2018) systematically reviewed the literature on the efficacy and safety of SNM and PTNS in non-neurogenic LUTDs and CPP not responsive to conservative treatments. In total, twenty-one studies were identified, met inclusion criteria, and were analyzed. The search demonstrated that neuromodulation is a practical method for decreasing incontinence episodes, pad use, voiding frequency, and improving bladder capacity and voiding volume, with an overall success rate ranging from 61% to 90% for SNM and 54% to 79% for PTNS. Additionally, SNM demonstrated high long-term efficacy rates for individuals with urgency incontinence, urgency frequency syndrome, and idiopathic retention refractory to conservative treatment. A low level of evidence was uncovered for IC/BPS, and the authors concluded it is impossible to give clinically compelling evidence for treating IC/BPS with SNM.

## Constipation

There is insufficient evidence to support SNS via neuromodulation for treating constipation. More high-quality studies are required to demonstrate clinical efficacy and utility and compare this technology to other treatments.

Through a multicenter, open-label, randomized trial performed in 2 hospitals, Heemskerk et al. (2024) compared SNM and conservative treatment for refractory idiopathic slow transit constipation (STC). The results of the trial showed that after 6 months, 22 (53.7%) participants were successfully treated with SNM versus 1 (3.8%) with PCT (odds ratio 36.4, 95% CI 3.4 387.5, $p = 0.003$). At 6 months, SNM individuals reported lower constipation severity and fatigue scores ($p < 0.001$), and improved QoL compared with PCT ($p < 0.001$). Eight serious AE (6 SNM, 2 PCT) and 78 AE (68 SNM, 10 PCT) were reported. The study is limited by the lack of long-term follow-up, leaving unclear long-term effectiveness for the technology. Additionally, the participants were allowed to use rescue medication during the recording of the defecation diary period to minimize worsening their state, Utility scores were unbalanced between the groups, and not all participants adhered to the medication use per protocol which was only discovered when the 3-week diaries were completed. Lastly, there may have been an underreporting of AEs in participants with PCT due to recall bias after 6 months of treatment. The authors concluded that SNM is a promising surgical treatment option in a homogenous group of adults and adolescents with refractory idiopathic STC.

In a 2023 systematic review by Heemskerk et al. the authors investigated the evidence on SNM for functional constipation to assess the effectiveness, safety and cost effectiveness for children and adults with refractory idiopathic STC. The exploration uncovered 67 studies that were chosen for full-text screening. For efficacy, one cross-over and one parallel-

group RCT was included, displaying conflicting results. Eleven studies on safety were included (four RCTs, three prospective cohort studies and four retrospective cohort studies). Overall infection rates varied between 0% and 22%, whereas reoperation rates varied between 0% and 29%. One trial-based economic evaluation was included, which concluded that SNM was not cost-effective compared with personalized conservative treatment at a time horizon of 6 months. The review findings are limited by the small number of available studies and the heterogeneity in terms of study populations, definitions of refractory idiopathic STC and study designs. The authors concluded that the evidence is insufficient and inconclusive to conclude the effectiveness, safety, and cost effectiveness of SNM for individuals with refractory STC (Zerbib et al. 2017 previously cited is included in this systematic review).

Pauwels et al. (2021) conducted a systematic overview of the current literature regarding neurostimulation modalities and their effects on chronic functional constipation in adults. The search produced seventeen studies deemed eligible for inclusion. The exploration uncovered several double-blinded cross-over RCTs demonstrating no significant impact of neurostimulation compared to sham stimulation for refractory constipation. Additionally, no significant improvement in constipation-related symptoms and QoL was uncovered in the review, suggesting the need for more powerful studies to decide the benefits of neurostimulation for constipation. The authors concluded that neurostimulation has not demonstrated benefits in filling the treatment gap for chronic functional constipation.

In 2017, Zerbib and colleagues led a multicenter, randomized, double-blinded, placebo-controlled, cross-over study (n = 36 individuals) to determine the efficacy of SNM for severe refractory constipation. Individuals selected were those with chronic constipation for more than a year, defined by two or fewer complete bowel movements per week, straining to evacuate at > 25% of attempts, or sensation of incomplete evacuation after defecation on > 25% of attempts. Participants were also included if they had no symptomatic response to standard therapies for at least three months. Of the 36 participants, 20 were offered permanent pulse generator implantation and assigned randomly in a cross-over design to active or sham stimulation at two eight-week intervals, a 2-week wash-out period separated the two trial stages. In random order, individuals were randomized to the two-interval cross-over with eight weeks of stimulation (on) and sham stimulation (off). After the second period, all individuals began the study's second phase and received active stimulation until week 50 after randomization. The primary outcome measured was the number of individuals who responded during the 'on' and 'off' stimulation periods. To consider the individual a responder to therapy, one had to achieve at least three bowel movements per week and/or > 50% improvement of symptoms. Secondary outcomes measured were the percentage of individuals with a response at one year, short- and long-term clinical and physiological factors associated with response to temporary and permanent SNM, the effects of SNM on an individual's daily bowel diary, Wexner score, QoL, VAS score, anorectal manometry parameters, and colonic transit time. No statistically significant difference between the 'on' and 'off' periods was demonstrated in the stool diaries or by the Wexner, VAS, or QoL score. A total of eleven individuals had sustained clinical response at one-year follow-up. Active stimulation had no significant effect compared with sham stimulation in both intention-to-treat (response in 12 of 20 *vs.* 11 of 20 participants, respectively) and per-protocol analyses. This randomized cross-over study did not show an effect of active stimulation compared with the absence of stimulation for individuals with refractory constipation who responded to PNE. Although the authors concluded that SNM is associated with improved QoL symptoms, the results do not support the recommendations of permanent implantation for individuals with refractory constipation who initially responded to temporary nerve stimulation (Included in the Pauwels et al. 2021 systematic review).

## Urinary Voiding Dysfunction and Fecal Incontinence Secondary to a Neurologic Disease Origin

There is insufficient evidence to support SNS via neuromodulation for treating urinary voiding dysfunction and fecal incontinence when secondary to a neurologic disease origin. More high-quality studies are required to demonstrate clinical efficacy and utility and compare this technology to other treatments.

The authors Carolus et al. (2025) assessed the efficacy of SNM for treating neurogenic overactive bladder (nOAB) for individuals with multiple sclerosis (MS). The primary outcome measured was clinical efficacy, defined as the implementation for an implantable pulse generator (IPG). The secondary outcomes measured were the Patient Global Impression of Improvement (PGI-I), the 3-day bladder diary parameters and the maintenance of efficacy within 5 years. The results of the study resulted in the median daily (9.0 to 7.0; $p < 0.001$) and nocturnal (2.5 to 1.0; $p < 0.01$) number of micturition/clean self-intermittent catheterization (CISC), the presence of urinary urgency (97% vs 58%; $p < 0.01$) and urinary incontinence (84% vs 25%, $p < 0.001$) significantly decreased at the end of the test phase. Efficacy was maintained at 5 years in 46% of cases. The authors concluded that for individuals with MS with nub, SNM exhibits clinical efficacy comparable to that observed in the non-neurological population.

Schwarztuch et al. (2024) aimed to evaluate the efficacy and safety of SNM for individuals with underlying neurologic conditions and compare outcomes to individuals with non-neurological conditions. Two groups were formed for the study, group one consisted of individuals with underlying neurological conditions, and group two were those with non-

neurological conditions. The participants bowel/bladder logs per and post operative were evaluated and compared to determine efficacy and safety. The results showed that there was not statistically significant in the difference between the groups regarding the indication for treatment. In both studies, the most common indication was NOUR with other common neurologic pathologies consisting of multiple sclerosis, disc disease, and spinal stenosis. During the follow-up, the device was removed in 4 (25.0%) and 10 (19.6%) of the people in group 1 and group 2, respectively (p = .912). There was no significant difference between the groups in the time till InterStim II removal (p = .905). All individuals with NOUR and clinical success in group 1 had an improvement of at least 75% from the baseline compared to 69% of those in group 2 (p = .42). Univariate analysis for individuals with NOUR demonstrated that maximal cystometric capacity below 430 mL and the presence of detrusor contraction at voiding were statistically significant predictors of successful SNM. The authors concluded that SNM could be considered in carefully selected individuals with neurogenic bladder and/or bowel dysfunction who are refractory to conservative treatments and willing to minimize self-catheterizations with a similar rate of efficacy, safety, and adverse outcomes to non-neurogenic patients. Despite the above-mentioned limitations of this work, it shows the feasibility of SNM for individuals with neurogenic issues with similar success rates to the non-neurogenic population. The conclusions drawn from these findings should be considered within the context of several limitations in the study.

Through a literature review, Wei et al. (2023) assessed the effectiveness and safety of SNM for neurogenic bladder (NB). A total of 291 individuals were included in 11 independent studies. The results of the review showed improvements of primary outcomes before and after SNM therapy were significant: incontinence episodes /24 h (WMD -2.52; 95% CI-3.14-1.90; p < 0.001), frequency/24 h (WMD-5.96; 95% CI -6.27, -5.66; p < 0.001), voiding volume (WMD 116.09 mL; 95% CI 86.68, 145.51; p < 0.001), cystometric capacity (WMD 129.84 mL; 95% CI 100.53, 159.15; p < 0.001), post-void residual volume (WMD-198.00 mL; 95% CI-264.60, -131.40; p < 0.001), clean intermittent self-catheterization/24 h (WMD-2.48; 95% CI -2.96, -2.00; p < 0.001). The authors concluded that this systematic review indicated that the SNM treatment for NB was safe and effective.

In 2023, Pires et al. conducted a systematic review and meta-analysis of the available literature and evaluated the therapeutic success of SNM for individuals with LARS. The outcomes measured were the number of successful definitive SNM implants, changes in bowel habits, incontinence scores, QoL scores, anorectal manometry data, and complications. A total of 164 individuals, with 91% responding successfully, who were submitted to percutaneous nerve evaluation (PNE) were included in the review. The results demonstrated an overall clinical success rate of 77% after permanent implantation. All other outcomes (frequency of incontinent episodes, fecal incontinence, and QoL scores) improved overall. The meta-analysis results showed a decrease in 10.11 incontinent episodes/week, a decrease of 9.86 points in the Wexner score, and an increase in QoL of 1.56 (pooled estimate). Changes in anorectal manometry were inconsistent. Local infection was the most common postoperative complication, followed by pain, mechanical issues, loss of efficacy, and hematoma. The authors concluded that the use of SNM for individuals with LARS is supported by the available evidence to be effective in improving QoL and total incontinence episodes.

## Clinical Practice Guidelines

### *American College of Gastroenterology (ACG)*

In 2021, the ACG supplied recommendations for managing benign anorectal disorders. The recommendations for SNS in treating constipation are derived from three RCTs. According to the ACG, the trials have shown no benefit of SNS in constipation (regardless of type). In addition, the long-term complication rate is considerable, with 61% reporting device-related AEs in a long-term (60 months) follow-up study. The ACG's recommendations for surgical treatment are as follows:

- SNS should be considered for individuals with FI who do not respond to conservative therapy (strong recommendation, moderate quality of evidence).
- Anal sphincteroplasty should be considered for individuals with FI who do not respond to conservative therapy and who have an anatomic sphincter defect (weak recommendation, low quality of evidence).
- Dynamic graciloplasty and artificial anal sphincter, where available, may allow the occasional patient with FI to avoid colostomy (weak recommendation, insufficient evidence).
- Colostomy is a last resort procedure that can markedly improve the QoL for individuals with severe or intractable FI (strong recommendation, low quality of evidence) (Wald et al., 2021).

### *American Gastroenterological Association (AGA)*

The AGA researched publications, including systematic reviews and expert opinions, to define the fundamental principles for surgical intervention and device-aided therapy for managing FI and defecatory disorders (DD). The AGA developed best practice advice #4, saying that SNS should be considered for individuals with moderate or severe FI in those whose symptoms have not responded after a three-month or longer trial of conservative measures, biofeedback therapy, and who do not have contraindications to these procedures. The AGA concluded that although small studies advocate that

SNS may improve rectal sensation for individuals with DD, rectal hyposensitivity, and tempt colonic propagating sequences, there is no evidence that SNS improves bowel symptoms or rectal evacuation in DD. From this evidence, the AGA developed best practice advice #13, stating that based on limited evidence, SNS should not be used for managing DD in clinical practice (Bharucha et al., 2017).

## *American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU)*

The 2023 AUA/SUFU guideline on the diagnosis and treatment of idiopathic OAB states:

- In patients with OAB who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy, clinicians should offer SNM, percutaneous tibial nerve stimulation, and/or intradetrusor botulinum toxin injection. (Moderate Recommendation; Evidence Level: Grade A) (Cameron et al. 2024).

The following guidance was offered: In individuals with signs and symptoms consistent with an OAB diagnosis, clinicians may offer SNS as third-line treatment in a carefully selected population characterized by severe refractory OAB symptoms or those not candidates for second-line therapy and are willing to undergo a surgical procedure. The authors found that SNS is a suitable therapy with long-lasting treatment effects but is counterbalanced by frequent and moderately severe AE's, including pain at the stimulator and lead sites, lead migration, infection/irritation, electric shock, the need for additional surgeries (a side effect occurring in greater than 30% of individuals), and periodic battery replacement. Additionally, individuals should be cognitively capable of operating the device and compliant with long-term treatment protocols. The authors note that given the adverse effects on QoL associated with severe OAB, the benefits of SNS appear to outweigh the risks and burdens. This guideline was updated by Lightner et al. (2019) with no change to the statement regarding SNS (Gormley et al., 2012, included in the 2019 Hayes report).

## *European Association of Urology (EAU)*

### EAU Guidelines on Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS)

- **Sacral nerve stimulation (neuromodulation)**
  - Summary of evidence: Sacral nerve neuromodulation is effective after failed conservative treatment for OAB/UUI, but no sham controls have been used.
  - Recommendation: Offer SNM to those who have UUI refractory to medical therapy and are willing to undergo surgical treatment.
- **Posterior tibial nerve stimulation**
  - Summary of evidence:
    - Prompted voiding, either alone or as part of a behavioral modification program, improves continence in elderly, care-dependent people.
    - The combination of bladder training with antimuscarinic drugs does not result in greater improvement of UI but may improve frequency and nocturia.
    - There is conflicting evidence on whether the addition of BT, electrostimulation, or biofeedback increases the effectiveness of PFMT alone.
    - Pre-operative PFMT does not confer additional benefit to men undergoing radical prostatectomy (1b).
    - Electrical stimulation may add benefit to PFMT up to six months.
    - There is limited evidence for the effectiveness of PTNS in male population.
    - There is no evidence that PTNS cures UUI in male population.
  - Recommendations:
    - Implement prompted voiding for patients with urinary incontinence (UI) where appropriate (strong).
    - Offer bladder training as a complementary treatment for UI (weak).
    - Offer pelvic floor muscle training alone or in combination with biofeedback and/or electrostimulation to men undergoing radical prostatectomy to speed recovery from UI.
- **Surgical treatment for underactive bladder**
  - Surgical options for male patients with non-neurogenic UAB/DU include benign prostatic surgery and SNM.
- **Sacral neuromodulation**
  - SNM has been reported to improve idiopathic urinary retention in women in long-term studies. However, only scarce evidence exists in men with DU or acontractile detrusor.
  - Summary of evidence:
    - In patients with Detrusor underactivity DU or a contractile detrusor and concomitant benign prostatic obstruction, de-obstruction procedures are associated with improvements in bladder contractility index, mean total International Prostate Symptom Score, mean maximum urinary flow, and mean postvoid residual volume.

        - Older age, lack of bladder outflow obstruction, concomitant detrusor overactivity, lower bladder contractility and use of transurethral resection of the prostate or photo vaporization instead of laser enucleation of the prostate are associated with worse post-operative outcomes after de-obstruction procedures.
        - SNM provides statistically significant improvement in terms of voided volume, postvoid residual, and median maximum flow rate in men with refractory DU and no BPO.
    - Recommendations:
        - Counsel patients with evidence of detrusor underactivity (DU) or acontractile detrusor and concomitant benign prostatic enlargement about the potential subjective and objective benefits of benign prostatic surgery.
        - Offer men with DU and no benign prostatic obstruction, test phase SNM (Baboudjian et al. 2024).

## EAU Guidelines on Management of Non-Neurogenic Female Lower Urinary Tract Symptoms

- **Sacral nerve stimulation (SNS)**
    - Summary of evidence:
        - SNS is more effective than continuation of failed conservative management for OAB/UUI, but no sham controls have been used.
        - SNS is as effective as onabotA 200 U injection at 24 months.
        - In patients who have been implanted, at least 50% improvement of UUI is maintained in ≥ 50% of patients and up to 40% may remain cured at five years. Surgical revision rates of 30-40% at three to four years is common.
    - Recommendation: Offer SNS to patients who have overactive bladder/UUI refractory to anticholinergic therapy (strong).
- **Follow-up of patients with an overactive bladder:**
    - Recommendations:
        - Offer early follow-up to women who have been commenced on anticholinergic or beta-3 agonist therapy.
        - Offer repeat injections of BTX as required, to women in whom it has been effective (refer to the manufacturer's guidance regarding the minimum timeframe for repeat injections).
        - Offer life-long surveillance to women who have a SNS implant to monitor for lead displacement, malfunction, and battery wear.
        - Offer cystoscopic surveillance to women who are ten years or more post-augmentation cystoplasty due to the small risk of malignancy.
- **Underactive bladder**
    - SNS improves voided volume and decreases PVR volume in women with DU.
    - Recommendation: Offer SNS to women with UAB refractory to conservative management.
- **Surgical management of functional bladder outlet obstruction**
    - SNS results in spontaneous voiding and a reduction in IC rate in the majority of female BOO patients in idiopathic urinary retention.
    - Recommendation: Offer SNS to women with functional BOO (Farag et al. 2025).

## Additional EAU Guidelines

A review of the evidence regarding short-term benefits and potential harms of therapeutic modalities for managing OAB syndrome in women was conducted under the auspices of the EAU, female non-neurogenic lower urinary tract symptoms guidelines panel. Results of the exploration uncovered that Antimuscarinics, and beta-3 agonists were meaningfully more effective than placebo across most outcomes, with beta-3 agonists being more effective at reducing nocturia events and antimuscarinics producing significantly higher adverse events. Onabotulinumtoxin-A (Onabot-A) was more effective than placebo across most outcomes but with pointedly higher rates of acute urinary retention/clean intermittent self-catheterization (six to eight times) and urinary tract infections (UTIs; two to three times). Onabot-A was also considerably better than antimuscarinics for curing UUI but not in the reduction of mean UUI episodes. Success rates of SNS were notably higher than those of antimuscarinics (61% vs 42%, p = 0.02), with comparable rates of adverse events. SNS and Onabot-A were not significantly different in efficiency outcomes. Satisfaction rates were higher with Onabot-A but with a higher rate of recurrent UTIs (24% vs. 10%). SNS correlated with a 9% removal and a 3% revision rate. The evidence supports using antimuscarinics and beta-3 agonists as first-line therapy, with beta-3 agonists conceivably initiating fewer side effects and being more beneficial for nocturia symptoms. Botulinum toxin injections and SNS are equivalent second-line options in terms of effectiveness but have a different adverse event profile, and their suitability should be discussed based on individual circumstances. The evidence for PTNS is still unclear (Farag et al., 2023).

The EAU developed guidelines regarding male urinary incontinence, which concluded that the evidence demonstrated surgery for UUI includes bladder wall injection of botulinum toxin A, SNS, and cystoplasty/urinary diversion. The EAU states: "Sacral nerve stimulation is effective after failed conservative treatment for OAB/UUI, but no sham controls have been used," and "Offer sacral nerve stimulation to patients who have UUI refractory to medical therapy and are willing to

undergo surgical treatment." (Gacci et al., 2022).

In 2022, the EAU developed guidelines for diagnosing and managing non-neurogenic female lower urinary tract symptoms (LUTS). Part 1 of the guidelines addresses diagnostics, 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. This report covers recommendations associated with LUTS and treating OAB, stress UI, and mixed UI. The recommendations outlined in this guideline related to SNS for treating LUTS are: Offer SNS to individuals with 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).

Part 2 of the guidelines addresses underactive bladder, bladder outlet obstruction, and nocturia to summarize managing these conditions. The recommendations are: "Offer sacral nerve stimulation to women with UAB refractory to conservative measures" and "Offer SNM to women with functional BOO." SNS is a valid option for female patients with DU, with proper patient selection (Arlandis et al., 2022).

## *International Continence Society (ICS)*

The ICS produced a best practice statement for using SNM authored by Goldman et al. (2018). A panel of urology, gynecology, and colorectal surgery experts describe SNM as an accepted therapy for refractory urinary urgency and frequency, UUI, NOUR, and FI. Per the expert panel members of the ICS, guidelines for urinary indications are as follows:

- SNM can be offered to individuals with OAB with or without incontinence who fail to respond to or are intolerant of conservative and medical therapies (Level of Evidence: I; Grade of Recommendation: A).
- SNM is an effective treatment for Fowler's Syndrome, voiding dysfunction, and NOUR (Level of Evidence: I; Grade of Recommendation: A).
- There is limited evidence supporting the role of SNM for individuals with interstitial cystitis (IC)/bladder pain syndrome (BPS). SNM is a choice for IC/BPS non-responsive to conservative therapies after appropriate assessment (Level of Evidence: III; Grade of Recommendation: C).
- There is a lack of evidence supporting SNM as a treatment choice for individuals with non-IC/BPS CPP (Level of Evidence: III; Grade of Recommendation: C).
- SNM is an option for symptom control for individuals with nLUTD who are at low risk of upper urinary tract deterioration (Level of Evidence: III; Grade of Recommendation: C).
- There is a lack of evidence to suggest that urodynamic testing can predict SNM outcomes (Level of Evidence: III; Grade of Recommendation C).
- The trial phase of SNM is the most valued tool for predicting the potential therapeutic success of SNM for urinary indications (Level of Evidence: II; Grade of Recommendation: B).
- In cases where SNM has been tried and failed, UDS may be considered to define further the underlying disorder (Expert Opinion).

Per the expert panel members of the ICS, guidelines for FI are as follows:

- SNM should be considered a second-line treatment possibility for bothersome FI for individuals who have failed conservative measures (Level of Evidence: II; Grade of Recommendation: B).
- An anal sphincter muscle defect is not a contraindication for SNM (Level of Evidence: III; Grade of Recommendation: C).
- Individuals with FI after Low Anterior Resection for rectal cancer may be candidates for SNM test lead implantation if conservative treatment fails (Level of Evidence: III; Grade of Recommendation: D).
- SNM is the preferred therapy for a proper individual with combined urinary and bowel symptoms (Level of Evidence: III; Grade of Recommendation: C).
- SNM for constipation should only be considered for individuals who have had symptoms for more than one year and have failed conservative treatment. No mechanically correct cause should exist (Level of Evidence: IV; Grade of Recommendation: D).
- A 2-3-week bowel diary is needed before the SNM test for bowel dysfunction. Anorectal physiology testing (manometry, anorectal sensation, volume tolerance, compliance) can be considered to help outline the elements of dysfunction and guide management (Level of Evidence: IV; Grade of Recommendation: C).

Absolute contraindications for SNM include:

- Insufficient clinical response to a therapeutic trial, incapability to operate the device with an absence of supportive caregivers who could otherwise offer assistance, and pregnant individuals (Level of Evidence: IV; Grade of Recommendation: C).

Relative contraindications for SNM include:
- Individuals with severe or rapidly progressive neurologic disease, individuals with established complete SCI, individuals with a known expected need for magnetic resonance imaging (MRI) of body parts below the head, and those with abnormal sacral anatomy (Level of Evidence: III; Grade of Recommendation: C).

Tips for the introduction of SNM to Individuals:
- SNM therapy should be discussed with all individuals as part of their bowel or bladder control treatment pathway (Level of Evidence: IV; Grade of Recommendation: C).
- Surgeons should evaluate the necessity for life-long follow-up, subsequent battery replacement, complications, and anticipated symptom improvement (Level of Evidence: IV; Grade of Recommendation: C).
- Preoperative counseling before SNM should consist of a discussion of risks, including implant site pain, infection, paresthesia, leg pain, and/or need for reprogramming or for device revision (Level of Evidence: 3; Grade of Recommendation: C).

Screening for success during the test period:
- Individuals who achieve 50% improvement in one or more of their troublesome urinary or bowel parameters during the PNE or Stage 1 test period may be offered complete system implantation.
- The PNE test stimulation period is typically seven days for the bladder and 10-21 days for bowel indications (Level of Evidence: III; Grade of Recommendation: 3).
- Stage 1 test period duration is typically 2-3 weeks. Stage 1 testing can be tried if PNE is questionable, particularly if a lengthier test period is required for screening. A repeat stage 1 test may be performed at the physician's discretion.
- The clinician should consider both sensory and motor responses important for success (Level of Evidence: IV; Grade of Recommendation: C).

Successful outcome – bladder and bowel:
- An individual satisfied with the treatment is considered to have a successful treatment outcome (Level of Evidence: III; Grade of Recommendation: C).
- For individuals with voiding dysfunction or nLUTD, further evaluations may be necessary to ensure the long-term safety of the urologic tract (Level of Evidence: III; Grade of Recommendation: C).

## *National Institute for Health and Care Excellence (NICE)*

In the 2023 NICE guidelines on Botulinum toxin type A injections into the urethral sphincter for idiopathic chronic NOUR current treatments for NOUR include urotherapy (that is, education and rehabilitation for bladder and bowel management), an alpha-adrenoreceptor blocker medicine, urethral dilatation, or clean intermittent catheterization. When the condition is refractory to these treatments, it may be treated with SNS or urinary diversion procedures.

The 2020 NICE guideline recommendations for a SNM system for treating refractory OAB are as follows:
- Evidence supports the case for adopting the SNM system for treating refractory OAB in the NHS. The SNM system improves symptoms and QoL. It has a longer battery life than the non-rechargeable system used in NHS clinical practice.
- The SNM system should be considered as an option for individuals with refractory OAB that is, when conservative treatment or treatment with medicine has not worked, in line with NICE's guidelines on UI and pelvic organ prolapse and LUTS. The SNM system is small and does not need to be removed for most MRI scans, so it may be useful for those with a low body mass index (BMI) or when an MRI is likely.

In the 2019 NICE guideline for assessing and managing UI and pelvic organ prolapse in women aged 18 and over, recommendations regarding SNS are as follows: offer percutaneous SNM to women after local or regional multidisciplinary teams (MDT) review of their OAB has not responded to non-surgical management including medications and:
- Symptoms have not responded to botulinum toxin (BTX) type A; or
- Individuals are unprepared to accept the risks of needing catheterization associated with BTX type A.

Additionally, NICE recommends discussing the long-term implications of percutaneous SNS with women, including:
- The need for test stimulation and the probability of the test's success.
- The risk of failure.
- The long-term commitment.
- The need for surgical revision.
- The adverse effects.

The NICE guideline also recommends telling women how to self-refer for prompt specialist review if symptoms return following a percutaneous SNS procedure.

Recommendations on clinical management of lower urinary tract symptoms in men from NICE (2015a) include:

- Consider offering implanted SNS to manage detrusor overactivity only to men whose symptoms have not responded to conservative management and drug treatments.
- Consider offering urinary diversion to manage intractable urinary tract symptoms only to men whose symptoms have not responded to conservative management and drug treatments and if cystoplasty or SNS is not clinically appropriate or is unacceptable to the individual.

NICE (2015b) produced interventional procedure guidance on SNS for idiopathic chronic NOUR, saying:

- Current evidence on the safety and efficacy of SNS for idiopathic chronic NOUR is adequate to support this procedure, provided those standard arrangements are in place for clinical governance, consent, and audit.
- During the consent process, clinicians should ensure that individuals understand the risk of complications, the need for further surgery, and the possible need for device removal and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Patient selection and treatment should be made in specialist units by clinical teams experienced in assessing, treating, and long-term care of individuals with bladder dysfunction and using SNS.
- NICE encourages the audit and reporting of long-term safety outcomes.

In the 2011 NICE interventional procedures guidance on Endoscopic Radiofrequency Therapy of The Anal Sphincter for Fecal Incontinence, NICE offered the following guidance regarding SNS:

- If conservative treatments have been unsuccessful, surgical options include sphincter repair, SNS, stimulated graciloplasty (creation of a new sphincter from other suitable muscles), anorectal or transabdominal implantation of an artificial anal sphincter, or permanent colostomy.

### *American Society of Colon and Rectal Surgeons (ASCRS)*

In 2023, the ASCRS compiled clinical practice guidelines for the management of fecal incontinence. These guidelines are based on the previous ASCRS Clinical Practice Guidelines for the Treatment of Fecal Incontinence published in 2015. The recommendations state:

- SNM may be considered as a first-line surgical option for incontinent patients with or without sphincter defects (recommendation strength: Conditional GRADE quality of evidence: Low) (Bordeianou et al. 2023).

The ASCRS Surgeons developed clinical practice guidelines titled 'Evaluation and Management of Constipation.' The Clinical Practice Guidelines Committee states that although the existing evidence advocates for SNM as an effective treatment for chronic constipation, most published reports were uncontrolled, with no evaluation of any other treatment modality. These studies also had no consistent definition of constipation or uniform technique to measure improvement. The committee suggests additional evidence is required to determine which measures should be used to evaluate success with test stimulation, whether individuals who fail test implantation should be implanted with a permanent stimulator, which criteria ought to be used to govern the success of permanent stimulation, and to delineate which individuals may profit from this treatment as opposed to other modalities. The ASCRS guideline regarding SNM for individuals with constipation reads as follows: SNM may be an effective treatment for individuals with chronic constipation and successful PNE test when conservative measures have failed; however, it is not currently approved by the US FDA for this condition in the United States. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B (Paquette et al., 2016).

The ASCRS formed clinical practice guidelines based on a review of published evidence for evaluating and managing individuals with FI. The authors reviewed all manuscripts, studies in adults, systematic reviews, and meta-analyses to develop the recommendations of these clinical practice guidelines, which the entire Clinical Practice Guidelines Committee reviewed. The GRADE system was utilized for the final grade of recommendation and approved by the Committee. The ASCRS states that SNM may be considered a first-line surgical option for incontinence for individuals with and without sphincter defects. This guideline was developed with the grade of recommendation: strong recommendation based on moderate-quality evidence, 1B (Paquette et al., 2015).

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

On June 18, 2025, Neuspera Medical Inc. announced that the FDA approved their premarket approval (PMA) application

for the Neuspera Sacral Neuromodulation System for treatment of UUI in individuals who have failed, could not tolerate, or were not a candidate for more conservative treatments. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P240031. (Accessed July 31, 2025)

FDA granted Premarket Approval (PMA) for InterStim in September 1997 (P970004) to treat OAB. FDA approved InterStim to treat urinary retention in April 1999 (S004). FDA approved the most recent InterStim device, InterStim Micro, in July 2020 (S302). InterStim's labeled indication reads as follows: [SNM] delivered by the InterStim™ system for Urinary Control is indicated for the treatment of urinary retention and the symptoms of OAB , including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in individuals who have failed or could not tolerate more conservative treatments. Medtronic InterStim Micro rechargeable sacral neuromodulation (SNM) system is the most recent model cleared and received FDA clearance in 2020. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970004. (Accessed July 31, 2025)

On September 6, 2019, the FDA granted PMA for the Axonics r-SNM® System (P190006). The Axonics r-SNM System is a rechargeable SNM system approved for sale in the United States, Europe, Canada, and Australia. This device is indicated for "The treatment of chronic fecal incontinence for individuals 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. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190006. (Accessed July 31, 2025)

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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 02/01/2026 | **Related Policies**<br>• Updated reference link to reflect the current policy title for *Gastrointestinal Disorders Diagnostic Procedures* |
| 01/01/2026 | **Template Update**<br>• Created shared policy version to support application to Oxford plan membership<br>**Supporting Information**<br>• Archived previous policy version 2025T0630I and SURGERY 125.5 |

# Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance,

CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.