

## Sacral Nerve Neuromodulation (Stimulation) for Pelvic Floor Dysfunction

Effective: March 1, 2024

Next Review: December 2024

Last Review: January 2024

### IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### DESCRIPTION

Sacral nerve neuromodulation involves the implantation of a permanent electrical stimulation device that modulates the neural pathways controlling bladder or rectal function.

### MEDICAL POLICY CRITERIA

**Note:** Sacral nerve neuromodulation should be initiated with a *trial period* of sacral nerve neuromodulation (peripheral nerve stimulation test) with a *temporarily implanted* lead and may be followed by *permanent implantation*. This policy addresses these services as one combined episode beginning with the temporary placement.

- I. Sacral nerve neuromodulation (including a *trial period* of sacral nerve neuromodulation [peripheral nerve stimulation test] with a *temporarily implanted* lead and, when used, the *permanent implantation*) may be considered **medically necessary** when one or more of the following criteria are met:
  - A. For the treatment of urinary incontinence and non-obstructive retention in patients who meet **all** of the following criteria (1. – 3.):

1. There is a diagnosis of at least one of the following:
  - a. Urge incontinence
  - b. Urgency-frequency syndrome
  - c. Non-obstructive urinary retention
  - d. Overactive bladder
2. There is documented failure or intolerance to at least 2 conventional conservative therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy); and
3. Incontinence is not related to a neurologic condition.

B. For the treatment of fecal incontinence in patients who meet **all** of the following criteria (1. - 5.):

1. There is a diagnosis of chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth;
2. There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy);
3. The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease;
4. Incontinence is not related to another neurologic condition; and
5. The patient has not had rectal surgery in the previous 12 months, or in the case of rectal cancer, the patient has not had rectal surgery in the past 24 months.

- II. Revision(s) or removal of an existing sacral nerve neuromodulation device may be considered **medically necessary** after the device has been placed.
- III. Replacement of all or part of an existing sacral nerve neuromodulation device and/or generator is considered **medically necessary** when the existing device and/or generator is malfunctioning, cannot be repaired, and is no longer under warranty.
- IV. Replacement of all or part of an existing sacral nerve neuromodulation device and/or generator is considered **not medically necessary** when Criterion III. is not met.
- V. Sacral nerve neuromodulation for the treatment of urinary incontinence, non-obstructive retention, and fecal incontinence is considered **not medically necessary** when Criterion I. is not met, including but not limited to stress incontinence and urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or diabetes with peripheral nerve involvement).
- VI. Sacral nerve neuromodulation for the treatment of all other indications is considered **investigational**, including but not limited to chronic pelvic pain and constipation.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine whether the policy criteria are met. If these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Documented applicable Diagnosis/Diagnoses and any neurological diagnoses present
- Documented failure or intolerance to conventional conservative therapies attempted as detailed in criteria I.A.2. and I.B.2.
- Documentation of surgical history within the last 24 months as applicable to fecal incontinence

## CROSS REFERENCES

1. [Pelvic Floor Stimulation as a Treatment of Urinary Incontinence](#), Allied Health, Policy No. 4
2. [Periurethral Transperineal Adjustable Balloon Continence Device](#), Medicine, Policy No. 176
3. [Subcutaneous Tibial Nerve Stimulation](#), Surgery, Policy No. 154

## BACKGROUND

Sacral nerve neuromodulation (SNM), previously known as sacral nerve stimulation is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. The SNM device consists of an implantable pulse generator (neurostimulator) that delivers controlled electrical impulses. The neurostimulator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. A remote control is provided to the patient to adjust the stimulation level.

Treatment using SNM is one of several alternative modalities for patients with fecal or urinary incontinence who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

Prior to implantation of the permanent device, patients undergo a peripheral nerve stimulation test to estimate potential response to SNM. This procedure is done under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for several days. This lead is connected to an external stimulator which is carried by patients in their pocket or on their belt. Patients then keep track of symptoms while the temporary device is functioning. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in incontinence frequency, they are deemed eligible for the permanent device. The permanent device is implanted with the patient under general anesthesia. An incision is made over the lower back and the electrical leads are placed in contact with the sacral nerve root(s). A second incision is made in the upper buttock where the neurostimulator is inserted and connected to the wire leads. The stimulator is turned on after the procedure is completed and the patient is provided a remote control to adjust the stimulation level. Manufacturers recommend the patients receive stimulation 24 hours per day, 7 days a week.

Newer generation stimulators have long life batteries (15-20 years) either requiring recharging weekly or are recharge free with an estimated recharge free life of 15 + years depending on level of stimulation.

## **REGULATORY STATUS**

### **Axonics Sacral Neuromodulation System**

In 2019, The Axonics Sacral Neuromodulation System received U.S. Food and Drug Administration (FDA) approval (PMA#: P190006) for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments. Product code: QON

In 2019, The Axonics Sacral Neuromodulation System received FDA approval (PMA#: P180046) for the treatment of urinary retention and the symptoms of overactive bladder, including urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments. Product code: EZW

Axonics currently has two devices:

- The Axonics R15™ System which has a rechargeable with a battery designed to last 15 years or more.
- The Axonics F15™ System which has a long life battery that does not require recharging (15 -20 year battery life). FDA Approved 3/7/22 for above indications.

Axonics SNM Therapy is contraindicated for patients who have not demonstrated an appropriate response to test stimulation; or patients who are unable to operate the Axonics SNM Systems.

### **Medtronic Interstim® Sacral Nerve Stimulation™ system**

In 1997, the Medtronic Interstim® Sacral Nerve Stimulation™ system received FDA approval (PMA# P970004) for marketing for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. In 1999 the device received FDA approval for the additional indications of urgency-frequency and urinary retention in patients without mechanical obstruction. Product Code: EZW

In 2006, the Medtronic Interstim® II System received FDA approval for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original system and is reported to be suited for those with lower energy requirements or small stature. The device also includes updated software and programming options.

In 2011, the Medtronic InterStim System received FDA approval (PMA#: P080025) for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments. Product Code: QON

In 2020, the Medtronic InterStim™ Micro system received FDA approval for above indications. This small device has a rechargeable battery designed to last 15 years. Recharging can be done 1x per week.

In 2022, the Medtronic InterStimX™ system received FDA approval for the above indications. This device does not require recharging and has a 15 year battery life when using low energy settings.

### **Virtis™ Sacral Neuromodulation System (Nuvectra)**

In 2023, the Virtis™ Sacral Neuromodulation System (Nuvectra) was approved by the FDA for treatment of urinary retention and symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency in patients who have failed more conservative treatments.

**Note:** Sacral Neuromodulation devices are not currently approved by the FDA for treatment of chronic pelvic pain or constipation.

**Note:** Sacral nerve neuromodulation should be distinguished from pelvic floor stimulation. Pelvic floor stimulation refers to electrical stimulation of the pudendal nerve. This therapy is addressed in a separate medical policy (see Cross References).

## **EVIDENCE SUMMARY**

Assessment of the safety and efficacy of sacral nerve modulation (SNM) as a treatment for urinary or fecal incontinence requires large, blinded, long-term randomized controlled trials to determine whether 1) the benefits of SNM outweigh any risks, and 2) whether SNM offers advantages over conventional conservative treatments. The appropriate control group(s) against which SNM should be compared is sham stimulation, on- versus off-phases in which patients act as their own controls, or conventional conservative therapies.

### **URINARY DYSFUNCTION**

#### **Urge Incontinence**

##### Systematic Reviews

Initially, the policy for SNM as a treatment of urge incontinence was based on a 1998 BlueCross BlueShield Association Technology Evaluation Center (TEC) assessment.<sup>[1]</sup> Based on a multicenter RCT<sup>[2]</sup> conducted as part of the FDA approval process, the TEC Assessment concluded that SNM reduced urge incontinence compared with control patients.

Brazzelli performed a review of articles published between 1966 and 2003 which included four randomized controlled trials (RCT) and 30 case series.<sup>[3]</sup> The authors reported that about 80% of patients in the randomized trials achieved greater than 50% improvement in their main incontinence symptoms after SNM compared with about 3% of controls receiving conservative treatments. The case series, which were larger but methodically less reliable, showed similar results. Benefits were reported to persist three to five years after implantation. The authors noted that technical changes over time were associated with decreased complication rates.

##### Randomized Controlled Trials

No new RCTs for urge incontinence were identified since the above systematic reviews were published.

##### Nonrandomized Studies

Groen (2011) reported five year follow-up results for patients (n=60) after SNM treatment for refractory idiopathic urge urinary incontinence.<sup>[4]</sup> Success was defined as at least a 50% decrease in the number of incontinent episodes or pads used per day. The success rate was 52 of 60 (87%) at one month and gradually decreased to 37 (62%) at five years. The number of women who were completely continent was 15 (25%) at one month and 9 (15%) at five years. At the five-year follow-up, SNM was still used by 48/60 (80%) women. A total of 57 adverse events were reported in 32 of 60 (53%) patients. The most frequent adverse events were hardware-related or pain or discomfort. There were a total of 23 reoperations in 15 patients. In most cases, pain problems were managed conservatively.

## **Urinary Urgency/Incontinence/Frequency/Overactive Bladder**

### Systematic Reviews

No recent systematic reviews were identified.

### Randomized Controlled Trials

In the multicenter randomized clinical study of 581 patients with a variety of urinary dysfunctions submitted to the FDA as part of the device approval process, 220 had significant urgency-frequency symptoms.<sup>[5]</sup> After six months of SNM therapy, 83% of patients with urgency-frequency symptoms reported increased voiding volumes with the same or reduced degree of frequency. At 12 months, 81% of patients had reached normal voiding frequency. Compared to a control group, patients with implants reported significant improvements in quality of life, as evaluated by the SF-36 health survey. The trial was well-designed, using standardized clinical and functional status outcomes measurements, and enrolled patients with severe urge incontinence who had failed extensive prior treatments. The magnitude of effect (approximately one-half of patients became dry, three-quarters experienced at least 50% reduction in incontinence) was fairly large, probably at least as great as with surgical procedures, and larger than expected from a placebo effect or conservative measures such as behavioral therapy or drugs. The therapy evaluation test, in which the device was turned off (ie, sham treatment was provided) and patients thus served as their controls, provided further evidence that the effect on incontinence was due to electrical stimulation and demonstrated that the effect of sacral nerve neuromodulation is reversible. The cohort analysis of the clinical trial provided some evidence that the effect of sacral nerve neuromodulation could be maintained for up to two years. There was a high rate of adverse events reported in this trial. Most were minor and reversible; however, approximately one-third of patients required surgical revision for pain at the operative sites or migration of the leads.

In 2016, Amundsen reported on a RCT comparing intradetrusor injection of onabotulinumtoxinA (n=192) with SNM (n=189) in women with refractory urgency urinary incontinence, defined as at least one supervised behavioral or physical therapy intervention and the use of a minimum of two anticholinergics (or inability to tolerate or contraindications to the medication).<sup>[6]</sup> In intention-to-treat analysis, onabotulinumtoxinA-treated patients had greater reductions in urge incontinence per day than SNM-treated patients: 3.9 vs 3.3 per day (mean difference: 0.63; 95% confidence interval [CI] 0.13 to 1.14, p=0.01). OnabotulinumtoxinA-treated patients had greater reductions in some overactive bladder-related quality of life questionnaire-related measures, although the clinical meaningfulness of the changes was uncertain. Patients in the onabotulinumtoxinA-treated group were more likely to have urinary tract infections (UTIs, 35% vs 11%; risk difference -23%, 95% CI -33% to -13%, p<0.001).

In 2014 Siegel published an industry-sponsored FDA-mandated postapproval randomized study and is known as the Insite trial.<sup>[7]</sup> This study compared SNM using a two-stage surgical procedure with standard medical therapy. Study inclusion criteria included a diagnosis of overactive bladder (OAB) (at least eight voids per day and/or at least two involuntary leaking episodes in 72 hours) and a failed trial of at least one anticholinergic or antimuscarinic medication. In addition, there needed to be at least one such medication that had not yet been attempted. Patients with neurologic diseases and with primary stress incontinence were excluded. A total of 70 patients were allocated to SNM and 77 to standard medical therapy. Of the 70 patients in the SNM group, 11 elected not to receive test stimulation with the tined lead and eight received the lead but did not receive a full system implant due to lack of response to a 14-day test stimulation period (response was defined as at least a 50% reduction in average leaks and/or voids). Patients in the medical treatment group tried the next recommended medication or restarted a discontinued medication. Therapeutic success was defined as at least a 50% improvement in average leaks/day or at least a 50% improvement in the number of voids per day or a return to fewer than eight voids per day. In an intention-to-treat analysis, the therapeutic success rate at six months was 61% in the SNM group and 42% in the standard medical treatment group; the difference between groups was statistically significant ( $p=0.02$ ). Quality of Life (QOL) at six months was a secondary outcome. Several validated QOL scales were used, and all favored the SNM group compared with the standard medical treatment group ( $p<0.002$  for all comparisons).

In 2014, Noblett published twelve-month follow-up results of the Insite trial. The analysis included patients included in the SNM group of initial RCT plus additional patients enrolled and implanted in the interim.<sup>[8]</sup> A total of 340 patients underwent test stimulation, 272 underwent implantation, and 255 completed 12 months of follow-up. In a modified completers' analysis, the therapeutic success rate was 82%. This modified completers' analysis included patients who were implanted and had either a baseline or 12-month evaluation, or withdrew from the trial due to a device-related adverse event or lack of efficacy. In an analysis limited to study completers, the therapeutic response rate was 85%. The Noblett analysis did not include data from the control group of patients receiving only standard medical therapy.

In 2014 Tang published the results of an RCT in which 240 women with OAB were randomized to receive tolterodine with ( $n=120$ ) or without ( $n=120$ ) sacral neuromodulation.<sup>[9]</sup> Participants were also divided into subgroups based on the presence or absence of urinary incontinence. The treatment period was three months; results were measured by voiding diaries and urodynamic parameters, in addition to psychological depression and anxiety scores. The group receiving SNM reported significantly greater improvements in the conditions of first desire to void, maximum cystometric capacity, daily average volumes, and daily single maximum voided volumes compared to the group receiving medication alone ( $p=.001$ ). The SNM group also reported greater decreases in self-rated depression and anxiety scales ( $p<0.001$ ). The authors concluded that combined treatment with SNM and tolterodine could improve the quality of life in women with OAB by decreasing voiding dysfunction symptoms and related depression and anxiety.

### Nonrandomized Studies

Chartier-Kastler (2022) published 3-year results from a prospective, observational, multicenter study from France (SOUNDS).<sup>[10]</sup> Patients with overactive bladder ( $N=229$ ) underwent InterStim implantation (either a first device or a replacement) and were followed for a mean of  $33.7 \pm 3.7$  months. During the 3-year follow-up, average daily voids and leaks were

significantly reduced (all  $p < 0.05$ ) and response (defined as  $\geq 50\%$  reduction in voids per day or return to normal voiding frequency) ranged from 72% to 86%. Quality of life scores were improved at all study visits. About half of the patients experienced adverse events, which were mostly minor, but surgical revision was required in 33% of patients. Lack of a control arm may limit the clinical applicability of these results.

Several groups have published results of the Axonics® Sacral Neuromodulation System for Urinary Urgency Incontinence Treatment (ARTISAN-SNM) study—a single arm, prospective, multicenter trial of the Axonics r-SNM System™.<sup>[11-13]</sup> All participants ( $n=129$ ) were implanted with a tined lead and the rechargeable sacral neuromodulation system in a nonstaged procedure. Efficacy data were collected using a 3-day bladder diary, the validated International Consultation on Incontinence Questionnaire Overactive Bladder quality of life (ICIQ-OABqol) questionnaire and a participant satisfaction questionnaire. Pezzell (2021) published a two year follow-up analysis and reported that 93% of the participants ( $n = 121$  Completers at two years) were therapy responders, of which 82% achieved  $\geq 75\%$  reduction in UUI episodes and 37% were dry (100% reduction).<sup>[13]</sup> Daily UUI episodes reduced from  $5.6 \pm 0.3$  at baseline to  $1.0 \pm 0.2$  at two years. Statistically significant improvements in ICIQ-OABqol were reported. Geynisman-Tan (2021) published a secondary analysis in Participants ( $n=124$ ) at one year.<sup>[11]</sup> Participants were classified as responders ( $n=110$ ) and non-responders (14) based on a  $\geq 50\%$  reduction in UUI episodes in a three-day period at one-month post-implant. Most participants reported being satisfied with the SNM treatment (68.5% were "very satisfied," 25.8% were "moderately satisfied," and 2.4% were "slightly satisfied). Twelve of the 14 "non-responders" continued to see improvements in symptom reduction from one month to one year; 9/14 (64%) were "responders" at one year with six reporting being "very satisfied" and one reporting being "moderately satisfied." McCrery (2020) reported at six-months that 90% of participants were therapy responders ( $\geq 50\%$  reduction in UUI episodes compared to baseline).<sup>[12]</sup> With a mean (+ SE) reduction of  $5.6 \pm 0.3$  at baseline to  $1.3 \pm 0.2$ . Participants experienced a clinically meaningful 34-point improvement on the ICIQ-OABqol questionnaire. There were no serious device related adverse events reported. The authors conclude that The Axonics r-SNM System™ demonstrates sustained safe and effective treatment for patients experiencing urinary urgency incontinence symptoms. They also report no unanticipated or serious device-related adverse events at two years.

Blok (2020) published the two year safety and efficacy outcomes using SNM for the treatment of Overactive Bladder (OAB) using the Axonics system.<sup>[14]</sup> Subjects ( $n=51$ ) with confirmed OAB were implanted with the Axonics system using a nonstaged procedure. At two years 90% of test responders (defined as subjects who were responders at one month) to respond based on voiding diary criteria. Satisfaction with therapy was reported by 93% of subjects and 86% found their charging experience acceptable. Of the urinary incontinence Test Responders, 88% continued to be responders at two years, and 28% were completely dry. There were no unanticipated (AEs) or serious device-related AEs. The authors conclude that the Axonics System® provides sustained clinically meaningful improvements in OAB subjects at two years.

There has also been interest in the use of SNM as a treatment of interstitial cystitis, a condition characterized by painful urinary urgency and frequency.<sup>[15-17]</sup> These studies reported a decrease in both urgency/frequency and pain. These patients would be considered candidates for SNM therapy based on the presence of urgency and frequency alone.

## Urinary Retention



## Systematic Review

A 2009 Cochrane review<sup>[18]</sup> described eight randomized studies on implanted devices for urinary storage and voiding dysfunction in adults. In spite of methodologic problems (e.g., generally poor-quality studies), the evidence “seems clear that continuous stimulation offers benefits for carefully selected people with overactive bladder syndrome and for those with urinary retention but no structural obstruction.” The authors concluded that while some people benefit, more research is needed to improve patient selection, to carry out the implant, and to find why so many fail.

In 2014, the Agency for Healthcare Research and Quality published a comparative effectiveness review focused on chronic urinary retention treatments.<sup>[19]</sup> The authors identified the previously described Cochran review as providing “low-strength evidence that neuromodulation improves the rate at which patients with Fowler’s syndrome can be catheter free after treatment,” but noted that there were few studies overall, and most were small and had other methodologic limitations.

## Randomized Controlled Trial

No new RCTs for urinary retention were identified since the above systematic review was published.

## **Complications of SNM for Urinary Dysfunctions**

A large prospective series by White focused on complications associated with SNM in 202 patients with urge incontinence, urinary urgency, or urinary retention.<sup>[20]</sup> At a mean follow-up of 37 months (range, 7 to 84), 67 patients (30%) had experienced adverse events that required either lead or implantable pulse generator revisions. Complications included pain (3%), device malfunction secondary to trauma (9%), infection (4%), postoperative hematoma (2%), and lead migration (6%). In addition, 5% of patients underwent elective removal, 4% had device removal due to lack of efficacy, and 2% required removal due to battery expiration. At the last follow-up, 172 patients (85%) had functional implanted units.

## **Section Summary**

Data from RCTs and case series with long-term follow-up provides sufficient evidence to conclude that SNM is effective and safe in selected patients with urge incontinence, overactive bladder, urgency-frequency syndrome, and non-obstructive urinary retention.

## **DEFECATION DYSFUNCTION**

### **Fecal Incontinence**

#### Systematic Reviews

In 2019, Simillis published a systematic review and meta-analysis of treatments for fecal incontinence (FI).<sup>[21]</sup> A total of 47 RCTs were included and 37 treatments were addressed. Overall, no treatment was ranked best or worst for any outcome. With respect to SNM, significant improvements compared to placebo were reported for incontinence scores.

A 2018 SR by Dulskas evaluated the literature on treatments for lower anterior resection syndrome.<sup>[22]</sup> The authors identified a total of 21 studies that met inclusion criteria, of which eight evaluated the use of SNM. Only one of the identified studies was determined not to be of

poor quality. Therefore, the authors concluded that high quality RCTs are needed to determine the efficacy of SNM.

A 2015 Cochrane review evaluated SNM for FI and constipation in adults.<sup>[23]</sup> This review included six trials assessing the effects of SNM for FI. Two parallel group trials found that SNM reduced the number of incontinence episodes when compared with optimal medical therapy or percutaneous tibial nerve stimulation. Three of the four included crossover trials found reductions in incontinence episodes during the SNM “on” period relative to the “off” period; in the other crossover trial, participants did not experience any episodes of FI during either period. The primary methodological quality issue noted was related to lack of clarity around randomization techniques and allocation concealment. The review authors concluded that there was limited evidence that SNM could improve continence in some patients with FI.

In 2016, the Agency for Healthcare Research and Quality published a comparative effectiveness review on treatments for FI.<sup>[24]</sup> There were 63 studies that met inclusion criteria for the review, and 53 surgical case series were reviewed for adverse events. There were 38 RCTs that assessed nonsurgical treatments and 12 that reviewed surgical interventions, including five studies of SNM. Regarding SNM, the authors concluded that the evidence was “insufficient because all five studies had moderate or high risk of bias, and none assessed the same treatment-outcome combination.”

In 2013, Thin published a SR of randomized trials and observational studies on SNM for treating FI.<sup>[25]</sup> A total of 61 studies met eligibility criteria; including at least 10 patients, having a clear follow-up interval and reporting the success rate of therapy based on a 50% or greater improvement in fecal incontinence episodes. Only two of the studies were RCTs.<sup>[26, 27]</sup> and 50 were prospective case series. Data from two studies with long-term follow-up could be pooled to calculate median success rates using an intention-to-treat analysis. These median success rates were 63% in the short term (no more than 12 months’ follow-up), 58% in the medium term (12 to 36 months), and 54% in the long term (>36 months). The per-protocol short-, medium-, and long-term success rates were 79%, 80%, and 84%, respectively.

In 2011, Maeda published a SR of studies on complications following permanent implantation of a SNM device for FI and constipation.<sup>[28]</sup> The authors identified 94 articles. The vast majority of studies addressed FI. A combined analysis of data from 31 studies on SNM for fecal incontinence reported a 12% suboptimal response to therapy (149 of 1,232 patients). A review of complications reported in the studies found that the most commonly reported complication was pain around the site of implantation, with a pooled rate of 13% (81/621 patients). The most common response to this complication was repositioning the stimulator, followed by explantation of the device and reprogramming. The second most common adverse event was infection, with a pooled rate of 4% (40/1025 patients). Twenty-five of the 40 infections (63%) led to explantation of the device.

In 2011, Tan published a meta-analysis of randomized trials and observational studies published between 2000 and 2008 on SNM for treating FI.<sup>[29]</sup> They identified a total of 34 studies that reported on at least one of their outcomes of interest and clearly documented how many patients underwent temporary and permanent SNM. Only one of these studies was an RCT; this was the study by Tjandra discussed earlier.<sup>[26]</sup> In the 34 studies, a total of 944 patients underwent temporary SNM and 665 subsequently underwent permanent SNM implantation. There were 279 patients who did not receive permanent implantation, and 154 of these were lost to follow-up. Follow-up in the studies ranged from 2 weeks to 35 weeks. In a

pooled analysis of findings of 28 studies, there was a statistically significant decrease in incontinence episodes per week with SNM compared to maximal conservative therapy (weighted mean difference: -6.83; 95% CI -8.05 to -5.60,  $p < 0.001$ ). Fourteen studies reported incontinence scores, and when these results were pooled, there was also a significantly greater improvement in scores with SNM compared to conservative therapy (weighted mean difference: -10.57, 95% CI -11.89 to -9.24,  $p < 0.001$ ).

A 2016 systematic review by Bielefeldt focused on the adverse events associated with SNM treatment of FI.<sup>[30]</sup> A literature search of PubMed and Embase was performed for studies that included at least five patients with fecal incontinence treated with SNM. The researchers additionally searched the FDA's Manufacturer and User Device Experience (MAUDE) database for reports from 2005 to October 2015. There were 45 articles included in the review that described distinct patient cohorts and provided information about adverse events. These included a total of 1,953 patients and a median follow-up time of 27 months. There were two studies with a total of 201 that provided the most detailed information.<sup>[31, 32]</sup> In these two studies, approximately 20% of the patients had their devices explanted by the end of follow-up and a substantial number required additional surgeries. There were five more studies that reported adverse events with less detail, and these reported a significantly lower incidence of such events. Information on infectious complications was reported in 44 studies with 1,953 patients, and the pooled rate of these was 5.1%. There were 39 studies with 1,810 patients that reported explant rates, with an average rate of 10.0%. Increases in explant rates were seen with increased follow-up duration. An overall re-operation rate of 18.6% was seen, based on data from 1,784 patients. According to the MAUDE database, there was an average of ten incidents per month related to the Interstim device in 2005. This rose to approximately 100 incidents per month within the next three years and stabilized until the year prior to FDA approval of the device as a treatment for fecal incontinence, and have since tripled. From August 1 - October 31, there were 1,684 problem reports received by the FDA, with 652 reports mentioning gastrointestinal issues as indications for SNM treatment and 278 reports specifically referring to fecal incontinence or bowel dysfunction. Most adverse events were reported within two years after device implantation.

In 2015, a systematic review was published that evaluated the impact of SNM on clinical symptoms and gastrointestinal physiology in patients with FI.<sup>[33]</sup> There were 81 studies included in the review, and the clinical outcomes assessed included frequency of fecal incontinence episodes, fecal incontinence severity score, and treatment success rates. A meta-analysis of the data from these studies was not possible, as most lacked a comparison group. Following SNM device implantation, 'perfect' continence was reported in 13% to 88% of patients. The majority of studies found a reduction in incontinence episodes per week (mean, -7.0; range, -24.8 to -2.7) and Wexner scores. The studies did not demonstrate any consistent, statistically significant effects of SNM on physiological parameters or identify any clinicophysiological factors that predicted success.

### Randomized Controlled Trials

No new RCTs for FI were identified since the above systematic review was published.

### Nonrandomized studies

Picciariello (2022) published a retrospective study to assess the long-term effectiveness of SNM treatment in patients with FI.<sup>[34]</sup> Of the patients ( $n=58$ ) who met the inclusion criteria, 36 (58%) participated in the study the remainder ( $n=22$ ; 38%) were lost to follow-up. The authors

report that 17 (27%) of patients included still experience efficacy with SNM, after a median follow-up of 13 years. The authors suggest that very long-term outcome further deteriorates with time compared with the 60–70% success rate reported at five years.

Jottard (2021) published the 6-month follow-up data for efficacy, clinical outcomes and ease of use of the Axonics rechargeable SNM (ArSNM) system in patients (n=15) with FI.<sup>[35]</sup> Patients were implanted with the SNM device using a single-stage procedure. At four weeks, 13 participants (87%) were test responders based on  $\geq 50\%$  reduction in FI episodes as documented on their bowel diary. Weekly FI episodes decreased from a median of 8 (5.8-20.3) at baseline to a median of 1.5 (0.4-4.5) at four weeks ( $p = 0.001$ ), and 1.5 (0-2.6) at six months ( $p = 0.001$ ), corresponding to 75% and 79% reduction in weekly FI episodes. Of the 13 subjects having  $\geq 50\%$  reduction in FI episodes at four weeks, 12 (PP = 92%) were therapy responders at six months. There were no unanticipated device or procedure-related adverse events. The authors conclude that the The ArSNM system provides safe and effective therapy in patients with FI at six months.

Desprez (2020) published results of a study that retrospectively analyzed prospectively collected data and found that long-term efficacy with SNM was maintained for at least 10 years post-implantation in approximately half of the patients treated for FI.<sup>[36]</sup> A similarly designed study by De Meyere (2020) in a single-center in Belgium demonstrated that the efficacy of sacral nerve stimulation in patients with fecal incontinence or low anterior resection syndrome was maintained for at least five years.<sup>[37]</sup>

Leo (2020) reported medium- and long-term outcomes following sacral nerve stimulation for FI.<sup>[38]</sup> This prospective observational study included 256 patients with medium-term results and, of those, 185 were followed up for long term outcomes. At the six-month follow-up, 65.2% (167/256) of patients showed a reduction of more than 50% in their St Marks fecal incontinence score and at the medium-term and long-term follow-ups it was 60.4% (142/235) and 62.1% (115/185), respectively. There was a reduction in median St Mark's score from baseline at six months ( $p < 0.00001$ ), which was maintained at the medium-term (110 months) and long-term (132 months) follow-ups. Twelve patients had lack of efficacy at the first postoperative follow-up, which was resolved with surgical correction in three patients and resulted in removal in the remainder. Of the 256 initial patients, 61 reported complications. This resulted in device removal for complications in 11 patients (4.2%), revisional surgery in 14 (5.4%), successful conservative treatment in 36 (14%), and a change of their SNS stimulation parameters in 51 (19.9%). Fourteen patients experienced wound infection/implant rejection.

In 2017, Koh reported on outcomes following SNM at a single Scottish center.<sup>[39]</sup> Of a total of 83 patients undergoing temporary SNM testing, 52 patients were permanently implanted. There were four failures, one removal due to cancer, seven infections, one lead migration, and three reports of post-operative pain or numbness.

Irwin (2017) assessed morbidity following SNM implantation for FI. Seventy-five patients were evaluated, 61 received insertion of a temporary SNM, and 40 received a permanent SNM.<sup>[40]</sup> Significant reduction in the Cleveland Clinic Incontinence Scores (14 pre-SNM to 9 post-SNM) and improvements in Role Physical, General Health, Vitality, Social Functioning, Role Emotional, Mental Health, and Mental Health Summary measures were reported.

Rice (2016) compared the commonly used staging procedure for evaluating candidacy for implantation of SNM to an office-based evaluation.<sup>[41]</sup> In this retrospective study, a total of 86 patients were evaluated, with 45 in the office-based evaluation group and 41 in the staged

group. The primary outcome was >50% improvement in Wexner score, resulting in patients progressing to permanent implantation. There was no significant difference in the primary outcome between groups or in the mean three-month Wexner score. Infection was significantly more likely in the staged group.

Patton (2016) evaluated medium-term outcomes from SNM patients at a single institution.<sup>[42]</sup> Of the 166 patients that underwent preliminary nerve stimulation testing, 112 had a permanent device implanted, and an additional 15 patients received a device without an initial testing phase for a total of 127 patients with SNM devices. The mean follow-up was 2.7 years (range, two months to 8.5 years), and 14 patients had the device removed and four had died, leaving 109 patients. Of these, 91 (83%) responded to the follow-up survey. There were significant improvements from baseline in St Mark's continence score (from 10.3 to 14.4,  $p < 0.01$ ), bowel control score, and fecal incontinence quality of life measures. Complications from the device included 12 infections, five of which required surgery, 17 lead dislodgements, and five rotated SNM devices that required repositioning.

Duelund (2016) published the results of a two-center prospective registry study that included 164 FI patients treated with SNM between 2009 and 2013.<sup>[43]</sup> The median follow-up in the study was 22 months (range, 1 to 50 months). There were improvements in Wexner incontinence scores and VAS impact on daily life. During follow-up, additional surgeries were required in 19.5% of patients. The most common complication was repositioning of the device due to pain or migration in 12.1% of patients, and infections leading to explantation were reported for 3% of patients. The same group also evaluated the effects of bilateral versus unilateral SNM for fecal incontinence treatment, and found no significant differences between groups.<sup>[44]</sup>

Altomare (2014) reported long-term outcomes (minimum of 60-month follow-up, median of 84-month follow-up) in patients implanted with a sacral nerve stimulator for FI.<sup>[45]</sup> Patients were identified in a European registry and surveyed. Long-term success was defined as maintaining the temporary stimulation success criteria, i.e., at least 50% improvement in the number of fecal incontinence episodes (or fecal incontinence symptom score) at last follow-up, compared with baseline. A total of 272 patients underwent permanent implantation of an SNM device and 228 were available for follow-up. A total of 194 of the 272 (71.3%) implanted patients maintained improvement in the long term.

Hull (2013) reported outcomes in 72 patients (60% of the 120 implanted patients) who had completed a five-year follow-up visit.<sup>[31]</sup> Sixty-four (89%) of the patients who contributed bowel diary data at five years had at least a 50% improvement from baseline in weekly incontinent episodes and 26 of the 72 patients (36%) had achieved total continence. It is uncertain whether outcomes differed in the 40% of patients who were missing from the five-year analysis.

Other case series have reported the experiences of patients with FI who were treated with sacral neuromodulation. These series are not summarized in depth here because methodological limitations do not permit conclusions on the safety and effectiveness of SNM for fecal incontinence. These limitations included patients with a variety of etiologies of fecal incontinence, including obstetric injury, spinal cord injury, prior surgery, sacral malformation, or idiopathic incontinence, lack of a comparator, and a wide range of follow-up periods (e.g., two months to 9.5 years). Thus, it is difficult to determine the complication rates or the durability of any benefits initially reported.

## Section Summary

With longer term results from two randomized controlled trials, prospective case series, and a pooled analysis of data from the RCTs and observational studies, evidence is considered sufficient to conclude that sacral nerve neuromodulation/stimulation improves outcomes when used for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy.

## **Constipation**

### Systematic Review

Pauwels (2021) published a SR evaluating the different modalities of neurostimulation and their effect on chronic functional constipation in adults.<sup>[46]</sup> Seventeen studies were included on SNM. Although multiple uncontrolled retrospective and prospective studies demonstrated positive effects of SNM in constipation, the 3 RCTs included in the analysis demonstrated no significant improvements in outcomes.

Pilkington (2017) published a SR on behalf of the NIHR CapaCiTY working group, Pelvic floor Society that assessed outcomes of sacral nerve stimulation in adults with chronic constipation.<sup>[47]</sup> Seventy articles were included, with a total of 375 patients. Morbidity rates were heterogeneous and varied from 13 to 34%. Device removal rates were also heterogeneous and ranged from 8 to 23%. Harms were inconsistently reported. Treatment success was reported between 57 and 87%. Reviewers concluded that the quality of studies was poor and therefore although the results were positive in favor of sacral nerve stimulation for chronic constipation, they urged caution.

The 2015 Cochrane review of SNM for fecal incontinence and constipation, described earlier, included two studies assessing SNM as a constipation treatment.<sup>[23]</sup> One trial, which included only two participants, found that the participants experienced a greater number of bowel movements per week when the device was on. The other trial, a larger randomized trial by Dinning, found that SNM did not affect the frequency of bowel movements.<sup>[48]</sup> The study included patients aged 18 to 75 years with slow transit constipation. Potentially eligible patients completed a three-week stool diary and, in order to continue participating, they needed to indicate in the diary that they had complete bowel movements less than three days per week for at least two of the three weeks. Patients with metabolic, neurogenic or endocrine disorders known to cause constipation were excluded. There were 57 patients that met eligibility criteria and had temporary percutaneous nerve evaluation (PNE), and 55 underwent permanent implantation. In random order, patients received active stimulation or sham stimulation. The primary outcome measure, determined by stool diaries, was a bowel movement with feelings of complete evacuation more than two days per week for at least two of three weeks; it was only assessed in phase 2. Compared with sham stimulation, 16 of 54 patients (29.6%) met the primary outcome during stimulation and 11 of 53 patients (20.8%) met it during sham stimulation; the difference was not statistically significant ( $p=0.23$ ). Other outcomes did not differ significantly by group. The review authors concluded that SMN did not improve constipation symptoms and there were some adverse events associated with its use.

In 2013, Thomas published a systematic review of controlled and uncontrolled studies evaluating sacral nerve stimulation for treatment of chronic constipation.<sup>[49]</sup> The authors identified 11 case series and two blinded cross-over studies. Sample sizes in the case series ranged from 4 to 68 patients implanted with a permanent SNM device; in 7 of the 11 studies,

fewer than 25 patients underwent SNM implantation. Among the two cross-over studies, one included two patients implanted with an SNM device. The other, a 2012 study by Knowles and colleagues, temporary stimulation was evaluated in 14 patients.<sup>[50]</sup> Patients were included if they were diagnosed with evacuatory dysfunction and rectal hyposensitivity and had failed maximal conservative treatment. Patients were randomized to two weeks of stimulation with the SNM device turned on and two weeks with the SNM device turned off, in random order. There was no wash-out period between treatments. The primary efficacy outcome was change in rectal sensitivity and was assessed using three measures of rectal sensory thresholds. The study found a statistically significantly greater increase in rectal sensitivity with the device turned on in two of the three measures. Among the secondary outcome measures, there was a significantly greater benefit of active treatment on the percentage of successful bowel movements per week and the percentage of episodes with a sense of complete evacuation. In addition to its small sample size, the study was limited by the lack of a wash-out period between treatments i.e., there could have been a carry-over effect when the device was used first in the “on” position. Moreover, the authors noted that the patients were highly selected; only 14 of the approximately 1800 patients approached met the eligibility criteria and agreed to participate in the study.

### Randomized Controlled Trials

One RCT has been published since the 2015 Cochrane review. This double-blind crossover trial, by Zerbib, included 36 patients (34 women) with refractory constipation, defined as at least two of the following criteria: fewer than three bowel movements per week, sensation of incomplete evacuation on more than a quarter of attempts, or straining to evacuate on more than a quarter of attempts.<sup>[51]</sup> This study defined a positive response to therapy as a more than 50% improvement in symptoms and/or at least three bowel movements per week. Of the 36 patients, 20 responded to the initial peripheral nerve evaluation and had a permanent stimulator implanted. Positive responses were seen in 12 of the patients during the active stimulation period and 11 of the patients during the sham stimulation period. Adverse events noted by the researchers included device-related pain in five patients and wound infection or hematoma in three patients, leading to device removal in two patients. SNM did not have a significant effect on colonic transit time. The authors concluded that the results of the study did not support the placement of SNM devices in patients with refractory constipation. The improvements seen with sham stimulation highlight the importance of control groups for comparison in studies of this technology.

Additionally, longer-term follow-up results to the study by Dinning<sup>[48]</sup> were published in 2016.<sup>[52]</sup> There were 53 patients that entered long-term follow-up, with one patient death. Adverse events or patient dissatisfaction lead to 44 patients withdrawing from the study by the end of the second year. Because of this, only ten patients met the primary outcome measure after one year, and only three patients met this measure after two years. There was no difference in colonic isotope retention at 72 hours at one-year follow-up.

### Nonrandomized Studies

A 2019 report by Widmann analyzed a prospective database of fecal incontinence and constipation patients treated with SNM therapy. A total of 101 patients underwent test stimulation, 79 received permanent implantation, and 57 were still receiving SNM at the end of follow-up. The five-year success rate was 88.2% (95% CI 80.1 to 97.0%) for fecal incontinence and 31.2% (95% CI 10.2 to 95.5%) in patients with isolated constipation. Complications

necessitation reinterventions were reported in 24 patients. Battery replacement was reported in 23 patients, and the median battery life was 6.2 years.

In 2017, Maeda published a prospective multicenter study.<sup>[53]</sup> Of the 62 patients who underwent test stimulation, 45 proceeded to permanent implantation and 18 were followed up through 60 months. Fourteen patients reported improved Cleveland Clinic constipation score, which was sustained at 60 months. Ten patients submitted a bowel diary. Analysis of these showed significantly increased defecations per week and reduced sensation of incomplete emptying. Device-related adverse events were reported in 61% of patients.

In 2010, Maeda published a retrospective review of 38 patients with constipation who received permanent SNM after a successful trial period.<sup>[54]</sup> The study focused on reportable events, defined as suboptimal outcomes (lack of or loss of efficacy) or adverse events. The authors did not report detailed criteria for temporary or permanent placement of an SNM device. At the time of chart review, a mean of 25.7 months had elapsed since implantation. A total of 58 reportable events were identified in 22 of the 38 (58%) patients. A median of two (range 1-9) events per patient were reported; 26 of 58 events (45%) were reported in the first six months after device implantation. The most common reportable events were lack or loss of efficacy (26 of 58 events, 45%), and pain (16 events, 28%). Twenty-eight (48%) of the events were resolved by reprogramming. Surgical interventions were required for 19 (33%) of the events, most commonly permanent electrode replacement (14 events). Three of 38 (8%) patients discontinued use of the device due to reportable events.

A prospective registry study published in 2016 evaluated the effects of SNM on antigrade continence enema use in pediatric patients with severe constipation.<sup>[55]</sup> There were 22 patients below age 21 included; 55% were male and the median age was 12 years. The median frequency of antigrade continence enema use dropped from seven per week to one per week at 12 months. The Fecal Incontinence Severity index improved after six months, while other outcomes, including laxative use, Gastrointestinal Symptom Scale, and Fecal Incontinence Quality of Life Scale did not change. Ten children received cecostomy/appendicostomy closure within two years.

Several small case series were identified that focused on patients with slow transit constipation.<sup>[56-59]</sup> While promising results were reported, these case series are inadequate to permit scientific conclusions due to methodological limitations such as lack of randomization and blinding, and lack of an adequate comparison group.

### Section Summary

Only three controlled cross-over studies are available; one study was very small and had only two patients, the second study had methodological limitations, and the third and largest study showed no statistical difference between sham and stimulation. In addition, there are several, mainly small, case series. There is insufficient evidence to permit scientific conclusions about the efficacy and safety of sacral nerve neuromodulation/stimulation for patients with constipation.

## **Chronic Pelvic Pain**

### Systematic Review

Tirlapur assessed the effectiveness of tibial and sacral nerve stimulation in the treatment of bladder pain syndrome (BPS) and chronic pelvic pain (CPP).<sup>[60]</sup> Authors included randomized



and prospective quasi-randomized controlled studies vs. sham nerve stimulation treatment or usual care of patients with CPP and BPS who underwent sacral or tibial nerve stimulation were included. Three studies with 169 patients treated with tibial nerve stimulation were included: two for CPP and one for BPS. There were improvements in pain, urinary and quality of life scores. There were no reported data for sacral nerve stimulation. Authors concluded that due to the quality of the literature, a large multi-centered clinical trial investigating the effectiveness of electrical nerve stimulation to treat BPS and CPP is recommended.

### Nonrandomized studies

Several case series have evaluated SNM for treating chronic pelvic pain. For example, in 2012 Martelluci reported on 27 patients with chronic pelvic pain (at least six months) who underwent testing for SNM implantation<sup>[61]</sup>. After a four-week temporary stimulation phase, 16 of 27 patients (59%) underwent implantation of an Interstim device. In the 16 implanted patients, mean pain on a visual analogue scale (VAS) was 8.1 prior to implantation and 2.1 at the six- and 12-month follow-ups. An earlier study by Siegel reported on 10 patients and stated that 9 of the 10 experienced a decrease in pain with SNM.<sup>[62]</sup>

### Section Summary

Data from several small case series with heterogenous patients represents insufficient evidence that sacral nerve neuromodulation/stimulation is safe and effective for treating chronic pelvic pain. RCTs are needed, with sham control groups, to assess the efficacy of neuromodulation/stimulation as a treatment of chronic pelvic pain.

## PRACTICE GUIDELINE SUMMARY

### **AMERICAN UROLOGICAL ASSOCIATION AND THE SOCIETY OF URODYNAMICS, FEMALE PELVIC MEDICINE & UROGENITAL RECONSTRUCTION**

The joint American Urological Association (AUA) and The Society of Urodynamics (SUFU) guidelines for non-neurogenic OAB in adults (updated in 2019) considers SNM an option for third-line treatment in carefully selected patients who failed conservative therapies and are characterized by severe OAB symptoms or those not considered candidates for pharmacologic therapy.<sup>[63]</sup> The strength of evidence was given a Grade C defined as low quality/low certainty based on observational studies that are inconsistent, small, or have other limitations that potentially confound interpretation of the data.

### **AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS**

A 2015 practice bulletin on urinary incontinence (replaced practice bulletin number 63, 2005; reaffirmed in 2018) from the American College of Obstetricians and Gynecologists (ACOG) stated, “sacral neuromodulation may be considered for patients with recalcitrant urinary urge incontinence who have failed other conservative measures, including bladder training, pelvic floor physical therapy with biofeedback, and pharmacologic treatment.”<sup>[64]</sup>

A 2019 ACOG practice bulletin (No. 210) on fecal incontinence included the following Level B (based on limited or inconsistent scientific evidence) recommendation: “sacral nerve stimulation can be considered as a surgical treatment option for women with fecal incontinence with or without anal sphincter disruption who have failed conservative treatments.”<sup>[65]</sup>

### **AMERICAN COLLEGE OF GASTROENTEROLOGY**

The 2014 clinical guideline on the management of benign anorectal disorders, including fecal incontinence, from the American College of Gastroenterology (ACG) found that "sacral nerve stimulation should be considered in [fecal incontinence] who do not respond to conservative therapy (strong recommendation, moderate quality of evidence)."<sup>[66]</sup> The 2021 updated ACG guidelines continue the recommendation for sacral nerve stimulation in patients with fecal incontinence refractory to medical therapy.<sup>[67]</sup> Additionally, due to a lack of evidence supporting efficacy and the risk of adverse events and complications, the 2021 ACG Panel states that sacral nerve stimulation "cannot be recommended in patients with constipation of any type".

## **AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS**

In 2015, the American Society of Colon and Rectal Surgeons released a clinical practice guideline for the treatment of fecal incontinence.<sup>[68]</sup> They stated that "sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects (Grade of Recommendation: Strong, based on moderate-quality evidence, 1B)."

In 2016, the Society released a clinical practice guideline for the management of constipation.<sup>[69]</sup> They stated "sacral neuromodulation may be an effective treatment for patients with chronic constipation and successful peripheral nerve evaluation test when conservative measures have failed; however, it is not currently approved by the US Food and Drug Administration for this condition in the United States (Grade of Recommendation: Weak, based on moderate quality evidence, 2B)."

## **SUMMARY**

There is enough research to show that sacral nerve neuromodulation/stimulation (SNM) can improve health outcomes and quality of life in some patients with urinary incontinence, non-obstructive urinary retention, overactive bladder or fecal incontinence. Therefore, SNM, including temporary and the potential permanent implantation, may be considered medically necessary for these conditions when the policy criteria are met.

A SNM device may require revision or removal after it has been placed. In these cases, revision may be medically appropriate to allow for the proper functioning of the device. Therefore, revision(s) to an existing sacral nerve neuromodulation device or removal of the device may be considered medically necessary after the device has been placed.

In certain situations, a SNM device may no longer be able to perform its basic function due to damage or wear. When a stimulator is out of its warranty period and cannot be repaired adequately to meet the patient's medical needs, replacement of the device may be medically appropriate. Therefore, replacement of all or part of SNM device and/or generator may be considered medically necessary when device replacement Criteria are met.

When a SNM device is in its warranty period or can be repaired or adapted adequately to meet the patient's medical needs, replacement of the device is not medically appropriate. Therefore, replacement of all or part of a sacral nerve neuromodulation device and/or

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generator is considered not medically necessary when device replacement Criteria are not met.

Sacral nerve neuromodulation/stimulation is considered not medically necessary for the treatment of urinary incontinence, non-obstructive urinary retention, and fecal incontinence in patients who do not meet criteria, including for individuals with urinary stress incontinence, or urge incontinence due to neurologic conditions such as multiple sclerosis, spinal cord injury, diabetes-related peripheral nerve conditions, and detrusor hyperreflexia because the procedure is not considered clinically effective or appropriate for these individuals.

There is not enough research to show that sacral nerve neuromodulation/stimulation (SNM) improves health outcomes for people with conditions other than urge incontinence, non-obstructive urinary retention, overactive bladder and fecal incontinence. Therefore, SNM is considered investigational for other conditions, including but not limited to chronic constipation and chronic pelvic pain.

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## CODES

**NOTE:** HCPCS code C1823 is NOT the correct code to use for reporting these services. Please refer to the codes listed below for guidance.

Codes	Number	Description
CPT	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
	0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters
	0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters
	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)

Codes	Number	Description
	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
	64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
	64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
	64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95971	;with simple spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter, programming by physician or other qualified health care professional
	95972	;with complex spinal cord, or peripheral (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
HCPCS	C1767	Generator, neurostimulator (implantable), nonrechargeable
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator

**Date of Origin:** February 1999