

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

Effective: February 1, 2019

Next Review: December 2019

Last Review: January 2019

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

Notes:

- 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.
- This policy only addresses the initial (temporary and permanent) placement of sacral nerve neuromodulation devices; it does not address device replacement.

- I. Sacral nerve neuromodulation may be considered **medically necessary** for the treatment of urinary incontinence and non-obstructive retention in patients who meet **all** of the following criteria (A-C):

- A. There is a diagnosis of at least one of the following:
 1. Urge incontinence
 2. Urgency-frequency syndrome
 3. Non-obstructive urinary retention
 4. Overactive bladder
 - B. There is documented failure or intolerance to at least two 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
 - C. Incontinence is not related to a neurologic condition.
- II. Sacral nerve neuromodulation may be considered **medically necessary** for the treatment of fecal incontinence in patients who meet **all** of the following criteria (A-E):
- A. There is a diagnosis of chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than six months or for more than 12 months after vaginal childbirth;
 - B. 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);
 - C. 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;
 - D. Incontinence is not related to another neurologic condition; and
 - E. 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.
- III. Sacral nerve neuromodulation for the treatment of all other indications is considered **investigational**, 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).

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

POLICY GUIDELINES

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.B. and II.B.

- 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. [Transanal Radiofrequency Treatment of Fecal Incontinence](#), Surgery, Policy No. 129

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 that delivers controlled electrical impulses. This pulse generator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet is kept by the patient and can be used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

Treatment using 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 voiding 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. According to data from the manufacturer, approximately 63% of patients have a successful peripheral nerve evaluation and are thus candidates for the permanent SNM.

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). The wire leads are extended through a second incision underneath the skin across the flank to the lower abdomen. Finally, a third incision is made in the lower abdomen where the pulse generator is inserted and connected to the wire leads. Following implantation, the physician programs the pulse generator to the optimal settings for that patient. The patient can switch the pulse generator between on and off by placing the control magnet over the area of the pulse generator for one to two seconds.

REGULATORY STATUS

In 1997, the Medtronic Interstim® Sacral Nerve Stimulation™ system received U.S. Food and Drug Administration (FDA) approval 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.

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 for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.

The Interstim device has not been specifically approved by FDA for treatment of chronic pelvic pain.

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.^[1] Based on a multicenter RCT^[2] 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 and 30 case series.^[3] The authors reported that about 80% of patients in the randomized trials achieved continence or 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

A 2011 series by Groen in reported the longest follow-up.^[4] A total of 60 patients had at least five years of follow-up after SNM for refractory idiopathic urge urinary incontinence. 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/Frequency

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, 220 had significant urgency-frequency symptoms.^[5] 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.

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).^[6] 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/ day (mean difference: 0.63; 95% 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.^[7] 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.^[8] 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.^[9] 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 ($p<.001$). 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

There has also been interest in the use of sacral nerve neuromodulation as a treatment of interstitial cystitis, a condition characterized by painful urinary urgency and frequency.^[10-12] These studies reported a decrease in both urgency/frequency and pain. These patients would be considered candidates for sacral nerve neuromodulation therapy based on the presence of urgency and frequency alone.

Urinary Retention

Systematic Review

A 2009 Cochrane review^[13] 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.^[14] 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

In the randomized clinical study submitted to the FDA as part of the approval process, 177 of 581 patients had urinary retention.^[15] Patients with urinary retention reported significant improvements in terms of volume catheterized per catheterization, a decrease in the number of catheterizations per day, and increased total voided volume per day. At 12 months post-implant, 61% of patients had eliminated the use of catheterization. Patients with implants also reported improved quality of life.

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.^[15] At a mean follow-up of 37 months (range, 7-84), 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 sacral nerve neuromodulation is effective and safe in selected patients with urge incontinence, urgency-frequency syndrome, and non-obstructive urinary retention.

DEFECATION DYSFUNCTION

Fecal Incontinence

Systematic Reviews

A 2018 SR by Dulskas evaluated the literature on treatments for lower anterior resection syndrome.^[16] 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 sacral nerve stimulation for fecal incontinence and constipation in adults.^[17] This review included six trials assessing the effects of SNM for fecal incontinence. 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 fecal incontinence 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 fecal incontinence.

In 2016, the Agency for Healthcare Research and Quality published a comparative effectiveness review on treatments for fecal incontinence.^[18] 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 systematic review of randomized trials and observational studies on SNM for treating fecal incontinence.^[19] 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.^[20,21] 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 (12-36 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.

A 2009 Cochrane review reported on three cross-over studies, two for fecal incontinence (n=34 and n=2, respectively) and one for constipation (n=2).^[22] This very limited evidence suggested that sacral nerve stimulation can improve continence in selected patients; however, it also reported that temporary, percutaneous stimulation for a two to three week period did not always successfully identify patients most likely to benefit from the stimulation. The authors concluded that larger, good quality randomized crossover trials are needed.

In 2011, Maeda published a systematic review of studies on complications following permanent implantation of a SNM device for fecal incontinence and constipation.^[23] The authors identified 94 articles. The vast majority of studies addressed fecal incontinence. 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 fecal incontinence.^[24] 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.^[20] 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% confidence interval [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 focused on the adverse events associated with SNM treatment of fecal incontinence.^[25] 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.^[26,27] 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 fecal incontinence.^[28] 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%-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 fecal incontinence were identified since the above systematic review was published.

Nonrandomized studies

In 2017, Koh reported on outcomes following SNM at a single Scottish center.^[29] 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 fecal incontinence. Seventy-five patients were evaluated, 61 received insertion of a temporary SNM, and 40 received a permanent SNM.^[30] 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.

A 2016 study by Rice compared the commonly used staging procedure for evaluating candidacy for implantation of SNM to an office-based evaluation.^[31] 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.

In 2016, Patton evaluated medium-term outcomes from SNM patients at a single institution.^[32] 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 – 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.

In 2016, Duelund published the results of a two-center prospective registry study that included 164 fecal incontinence patients treated with SNM between 2009 and 2013.^[33] The median follow-up in the study was 22 months (range, 1-50 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.^[34]

A 2014, study by Altomare 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 fecal incontinence.^[35] 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.

In 2013, Hull reported outcomes in 72 patients (60% of the 120 implanted patients) who had completed a five-year follow-up visit.^[26] 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.

Mellgren (2011) reported on the long-term effectiveness and safety of sacral nerve stimulation for fecal incontinence in a large prospective multicenter study.^[36] One hundred thirty-three patients underwent test stimulation with a 90% success rate. Mean length of follow-up was 3.1 (range, 0.2-6.1) years, with 83 patients completing all or part of the 3-year follow-up assessment. At three years follow-up, 86% of patients ($P < .0001$) reported $\geq 50\%$ reduction in the number of incontinent episodes per week compared with baseline and the number of incontinent episodes per week decreased from a mean of 9.4 at baseline to 1.7. Perfect continence was achieved in 40% of subjects. Sacral nerve stimulation had a positive impact on the quality of life. There were no reported unanticipated adverse device effects associated with sacral nerve stimulation therapy.

In 2011, Maeda in Denmark published a retrospective review of prospectively collected data from 176 patients who underwent permanent SNM for fecal incontinence.^[37] A total of 245 patients had initially undergone temporary stimulation. The review focused on reportable events, defined as suboptimal outcomes (lack of or loss of efficacy) or adverse events. At the time of data collection, a median of 47 months had elapsed since implantation of InterStim ($n=106$) and 21 months in patients implanted with InterStim II ($n=70$). A total of 592 reportable events were identified in 150 of the 176 (85.2%) patients after a median of 11 months using the implantable devices. Overall, interventions were able to successfully resolve 63 of 212 events (30%). The five-year follow-up results from this study was published in 2014.^[27] At this point, 60 of the 101 patients reported a favorable outcome and 41 reported an unfavorable outcome, with 24 of these patients having had their devices removed or permanently switched off. There were 521 reportable events recorded from 94 of the patients (93.1%)

Michelsen reported on the outcome of percutaneous nerve evaluation tests and sacral nerve stimulation for the treatment of fecal incontinence from a single center covering a period of six years.^[38] A total of 177 patients with fecal incontinence underwent a percutaneous nerve evaluation test. Of these patients, 142 (80%) had a positive test, including 21 of 25 (84%) patients who required a repeat percutaneous nerve evaluation test. Because of a functional failure, 16 patients underwent a revision of the permanent electrode. Of 126 patients, 15 (12%) have undergone an explantation, with an infection rate of only 1.6%. Overall, after a median follow-up of 24 (range, 3-72) months, the median Wexner incontinence score decreased from 16 (range, 6-20) to 10 (range, 0-20) ($P < .0001$).

In 2010, Wexner and others determined the safety and efficacy of sacral nerve stimulation.^[39] A total of 133 patients underwent test stimulation with a 90% success rate, and 120 (110 females) of a mean age of 60.5 years and a mean duration of FI of 6.8 years received chronic implantation. Mean follow-up was 28 (range, 2.2-69.5) months. At 12 months, 83% of subjects achieved therapeutic success (95% confidence interval: 74%-90%; $P < 0.0001$), and 41% achieved 100% continence. Therapeutic success was 85% at 24 months. Incontinent episodes decreased from a mean of 9.4 per week at baseline to 1.9 at 12 months and 2.9 at two years. There were no reported unanticipated adverse device effects associated with InterStim Therapy.

Other small case series ($n = 10-40$) have reported the experiences of patients with fecal incontinence 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 and the wide range of follow-up periods (e.g., two months– 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

A 2017 systematic review by Pilkington on behalf of the NIHR CapaCiTY working group, Pelvic floor Society assessed outcomes of sacral nerve stimulation in adults with chronic constipation.^[40] They identified seven articles, reporting on 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.^[17] 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 et al., found that SNM did not affect the frequency of bowel movements.^[41] 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.^[42] 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.^[43] 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.^[44] 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^[41] were published in 2016.^[45] 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

In 2017, Maeda published a prospective multicenter study.^[46] 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.^[47] 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.

In 2010, Kamm published findings on a prospective study that included patients who failed conservative treatment for intractable idiopathic constipation and underwent 21 days of test stimulation.^[48] Sixty-two patients who had idiopathic chronic constipation lasting at least one year and had failed medical and behavioral treatments were included. Forty-five of the 62 (73%) met criteria for permanent implantation during the 3-week trial period. After a median follow-up of 28 months (range 1-55 months) after permanent implantation, 39 of 45 (87%) patients were classified as treatment successes (i.e., met same improvement criteria as were used to evaluate temporary stimulation). There was a significant increase in the frequency of bowel movements from a median of 2.3 per week at baseline to 6.6 per week at latest follow-up ($p < 0.001$). The frequency of spontaneous bowel movements (i.e., without use of laxatives or other stimulation) increased from a median of 1.7 per week at baseline to 4.3 per week at last follow-up; $p = 0.0004$. A total of 101 adverse events were reported; 40 (40%) of these were attributed to the underlying constipation or an unrelated diagnosis. Eleven serious adverse events related to treatment were reported (the authors did not specify whether any patients experienced more than one serious event). The study has been criticized for including a large number of patients who had more than two bowel movements per week at study entry.

A prospective registry study published in 2016 evaluated the effects of SNM on antigrade continence enema use in pediatric patients with severe constipation.^[49] 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.^[50-52] 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. This represents 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).^[53] 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 sacral neuromodulation 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^[54]. After a 4-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 6- 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.^[55]

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 (AUA) AND THE SOCIETY OF URODYNAMICS, FEMALE PELVIC MEDICINE & UROGENITAL RECONSTRUCTION (SUFU)^[56]

The 2014 joint American Urological Association (AUA) and The Society Of Urodynamics (SUFU) guidelines for non-neurogenic OAB in adults 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. The recommendation was graded as an “option,” defined as a non-directive statement that leaves the decision up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or uncertain. 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.

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 urge incontinence, urgency-frequency syndrome, 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.

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

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57. BlueCross BlueShield Association Medical Policy Reference Manual "Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction " Policy No. 7.01.69

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	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	
	64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	
	64585	Revision or removal of peripheral neurostimulator electrode array	
	64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling.	
	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	
	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
		L8679	Implantable neurostimulator, pulse generator, any type
L8680		Implantable neurostimulator electrode, each	
L8681		Patient programmer (external) for use with implantable programmable neurostimulator pulse generator	
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