Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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(See policy history boxes for previous effective dates)

Title: Sacral Nerve Neuromodulation/Stimulation

Description/Background

Sacral nerve neuromodulation (SNM), also known as sacral nerve stimulation (SNS), is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This policy addresses use of SNM in the treatment of urinary or fecal incontinence, urinary or fecal nonobstructive retention and chronic pelvic pain in patients with intact neural innervation of the bladder and/or rectum.

Urinary and Fecal Incontinence

Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes and is a prominent symptom of interstitial cystitis (also called bladder pain syndrome). Urinary retention is the inability to completely empty the bladder of urine. Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

Treatment

Treatment using SNM, also known as indirect SNS, is one of several alternative modalities for patients with fecal or urinary incontinence (urge incontinence, significant symptoms of urgency-frequency, or nonobstructive urinary retention) who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies. Urge incontinence is defined as leakage of urine when there is a strong urge to void.

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.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to SNM. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for 4-7 days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device.

The second type of testing is a 2-stage surgical procedure. In the first stage, a quadripolar-tined lead is implanted (stage 1). The testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, they can proceed to stage 2 of the surgery, which is permanent implantation of the neuromodulation device. The 2-stage surgical procedure has been used in various ways. These include its use instead of PNE, for patients who failed PNE, for patients with an inconclusive PNE, or for patients who had a successful PNE to further refine patient selection.

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 1–2 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. FDA product code: EZW.

Note: This policy does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. In addition, this policy does not address devices that provide direct SNS

in patients with spinal cord injuries. An example of such a device is the NeuroControl VOCARE® Bladder Control System/Finetech Brindley Bladder system sacral nerve stimulator, which is intended for patients with complete spinal cord injury and neurogenic bladder.

Medical Policy Statement

The safety and effectiveness of sacral nerve stimulation for specific types of urinary and/or fecal incontinence have been established. It may be considered a useful therapeutic option for patients meeting specified criteria.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Urinary Incontinence and Non-obstructive Retention

Inclusions:

A. A *trial* period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead is established in patients who meet **all** of the following criteria:
   1. There is a diagnosis of at least 1 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 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).
      a. The patient is an appropriate surgical candidate.
      b. Incontinence is not related to a neurologic condition.

B. Permanent implantation of a sacral nerve neuromodulation device is established in patients who meet all of the following criteria:
   1. All of the criteria in A (1-4) above are met.
   2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Exclusions:

Other urinary/voiding applications of sacral nerve neuromodulation are considered experimental/ investigational, including but not limited to treatment of

- Stress incontinence or
- Urge incontinence due to a neurologic condition, (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury or other types of chronic voiding dysfunction).

Fecal incontinence

Inclusions:

Sacral nerve neuromodulation is established for the treatment of fecal incontinence when all of the following criteria are met:

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered established in patients who meet all of the following criteria:
   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 patient is an appropriate surgical candidate.
   4. 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.
   5. Incontinence is not related to a neurologic condition.
   6. The patient has not had rectal surgery in the previous 12 months, or in the case of cancer, the patient has not had rectal surgery in the past 24 months.

B. Permanent implantation of a sacral nerve neuromodulation device may be considered established in patients who meet all of the following criteria:
   1. All of the criteria in A (1-6) above are met.
   2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Exclusions:
Sacral nerve neuromodulation is experimental/investigational for the treatment of chronic constipation or chronic pelvic pain.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

A4290	E0745	E1399	L8680	L8685	L8686
L8687	L8688	64561	64581	64585	95970
95971	95972				

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition

improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

URINARY INCONTINENCE

Clinical Context and Therapy Purpose

Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes and is a prominent symptom of interstitial cystitis (also called bladder pain syndrome). Urinary retention is the inability to empty the bladder of urine completely.

The purpose of sacral nerve neuromodulation in patients with urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does sacral nerve neuromodulation in patients with urinary incontinence improve net health outcomes?

The following **PICO** was used to select literature to inform this review.

Patients

The relevant population of interest is patients with urinary incontinence.

Intervention

The treatment being considered is sacral nerve neuromodulation, which is performed by a urologist or urogynecologist in an outpatient clinical or surgical setting.

Comparators

The comparator of interest is pharmacologic treatment.
Patients with urinary incontinence are managed by urologists or urogynecologists in an outpatient clinical setting.

Outcomes

The outcomes of interest are symptoms, morbid events, and treatment-related morbidity. Positive outcomes include reduction or elimination of episodes of incontinence without complications from the device or implantation procedure.

Negative outcomes would be infection, bleeding, pain, and lead breakages, and lack of improvement in incontinence.

Although no set standard for length of follow-up has been established, the existing literature evaluating sacral nerve neuromodulation for urinary incontinence has lengths of follow-up ranging from 6 months to 5 years. Follow-up of at least 1 year would be preferred.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

Several RCTs on SNM for urinary incontinence have been conducted. The larger study was sponsored by Medtronic and submitted to the U.S. Food and Drug Administration as part of the approval process.[3] Findings have not otherwise been published. Based on this RCT, the 1998 TEC Assessment concluded that SNM reduced urge incontinence compared to control patients.[1] 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 the 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 from conservative measures such as behavioral therapy or drugs. The therapy evaluation test, in which the device is turned off (i.e., sham treatment was provided) and patients thus serve as their own controls, provided further evidence that the effect on incontinence is due to electrical stimulation and demonstrates that the effect of SNM is reversible. The cohort analysis of the clinical trial provides some evidence that the effect of SNM is maintained for up to 2 years. There was a high rate of adverse events reported in this clinical trial. Most of the adverse events 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 this RCT, 177 of 581 patients had urinary retention. 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 postimplant, 61% of patients had eliminated the use of catheterization. A total of 220 of 581 (38%) had significant urgency-frequency symptoms. After 6 months, 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 Short Form-36 (SF-36) Health Survey.

An additional prospective RCT of 44 patients with urge incontinence was published in 2000.[4] At 6 months, the implant group showed significantly greater improvement on standardized clinical outcomes, as compared to those receiving conservative therapy. The magnitude of effect was substantial.

Siegel et al (2015) published results of an industry-sponsored FDA-mandated post-approval study. This study compared SNM using a 2-stage surgical procedure with standard medical therapy.[5] Study inclusion criteria included a diagnosis of overactive bladder (at least 8 voids per day and/or at least 2 involuntary leaking episodes in 72 hours) and a failed trial of at least 1 anticholinergic or antimuscarinic medication. In addition, there needed to be at least 1 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 8 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 per day or at least a 50% improvement in the number of voids per day or a return to fewer than 8 voids per day. In an intention-to-treat analysis, the therapeutic success rate at 6 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). QOL at 6 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).

Twelve-month follow-up of the Insite trial was published by Noblett et al in 2016.[6] The analysis included patients from in the sacral nerve stimulation (SNS) group of initial RCT plus additional patients enrolled and implanted in the interim. A total of 340 patients underwent test stimulation, 272 underwent implantation, and 255 completed 12 months of follow-up. 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 2016, Amundsen et al reported on an RCT comparing intradetrusor injection of onabotulinumtoxinA (n=192) with SNM (n=189) in women with refractory urgency urinary incontinence, defined as at least 1 supervised behavioral or physical therapy intervention and the use of a minimum of 2 anticholinergics (or inability to tolerate or contraindications to the medication).[7] In ITT analysis, patients in the onabotulinumtoxinA-treated group had greater reductions in urge incontinence per day (3.9 per day) than in the SNM-treated group (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 QOL 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 (35% vs. 11%; risk difference, -23%; 95% CI, -33% to -13%; p<0.001).

Case Series

In addition to the RCTs, case series have been published and some have had longer follow-up than the RCTs. For example, a 2011 series by Groen et al in The Netherlands reported the longest follow-up.[8] Sixty patients had at least 5 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 (87%) of 60 at 1 month and gradually decreased to 37 (62%) at 5 years. The number of women who were completely continent was 15 (25%) at 1 month and 9 (15%) at 5 years. At the 5-year follow-up, SNM was still used by 48 (80%) of 60 women. Fifty-seven adverse events were reported in 32 (53%) of 60 patients. The most frequent were hardware-related or pain or discomfort. There were 23 reoperations in 15 patients. In most cases, pain problems were managed conservatively.

Findings from a large prospective series were reported in 2009 by White et al.[9] The series focused on complications associated with SNM in 202 patients with urge incontinence, urinary urgency, or urinary retention. 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: Urinary Incontinence

In summary, data from RCTs and case series with long-term follow-up suggest that SNM reduces symptoms of urge incontinence, urgency-frequency syndrome, non-obstructive urinary retention, or overactive bladder in selected patients.

FECAL INCONTINENCE

Clinical Context and Therapy Purpose

Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

The purpose of sacral nerve neuromodulation in patients with fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does sacral nerve neuromodulation in patients with fecal incontinence improve net health outcomes?

The following **PICO** was used to select literature to inform this review.

Patients

The relevant population of interest is patients with fecal incontinence.

Intervention
The treatment being considered is sacral nerve neuromodulation, which is performed by a gastroenterologist in an outpatient clinical or surgical setting.

Comparators
The comparator of interest is continued conservative therapy, such as dietary modification, bulking, or pharmacologic treatment.

Patients with fecal incontinence are managed by gastroenterologists in an outpatient clinical setting.

Outcomes
The outcomes of interest are symptoms, morbid events, and treatment-related morbidity. Positive outcomes include reduction or elimination of episodes of incontinence without complications from the device or implantation procedure.

Negative outcomes would be infection, bleeding, pain, and lead breakages, and lack of improvement in incontinence.

Although no set standard for length of follow-up has been established, the existing literature evaluating sacral nerve neuromodulation for fecal incontinence has lengths of follow-up ranging from 2 weeks to 84 months. Follow-up of at least 1 year would be preferred.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Systematic Reviews
In 2015, Thaha et al published a Cochrane review on SNS for fecal incontinence and constipation in adults, which included randomized, quasi-randomized, and crossover trials.[10] For fecal incontinence, reviewers included 6 trials of SNM (n=219 patients), 2 of which used parallel-group designs (Thin et al [2015], Tjandra et al [2008]; the latter described below); the others used crossover designs. The primary methodologic quality issue noted was a lack of clarity involving randomization techniques and allocation concealment. Reviewers concluded: "The limited evidence from the included trials suggests that SNS can improve continence in a proportion of patients with faecal incontinence."

In 2013, Thin et al published a systematic review of randomized trials and observational studies on SNM for treating fecal incontinence.[11] Sixty-one studies met eligibility criteria; assessing 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. Data from 2 studies with long-term follow-up could be pooled to calculate median success rates using an ITT analysis. These median success rates were 63% in the short term (≤12 months of 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.

Previously, in 2011, Tan et al published a meta-analysis of studies SNM for treating fecal incontinence.[12] 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 (Tjandra et al [2008]). In the 34 studies, a total of 944 patients underwent temporary SNS and 665 subsequently underwent permanent SNS 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 SNS compared to conservative therapy (WMD= -10.57, 95% CI: -11.89 to -9.24, p<0.001).

In 2011, Maeda et al published a systematic review of studies on complications following permanent implantation of a SNS device for fecal incontinence and constipation.[13] Reviewers identified 94 articles. Most addressed fecal incontinence. A combined analysis of data from 31 studies on SNS for fecal incontinence reported a 12% suboptimal response to therapy (149/1232 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 device explantation and reprogramming. The second most common adverse event was infection, with a pooled rate of 4% (40/1025 patients). Twenty-five (63%) of the 40 infections led to device explantation.

Randomized Controlled Trials

In 2008, Tjandra et al published an RCT with 120 patients with severe fecal incontinence.[14] Patients were randomly assigned to receive sacral nerve stimulation or best supportive therapy, consisting of pelvic floor exercises with biofeedback, bulking agents, and dietary management with a team of dieticians. Exclusion criteria included neurologic disorders and external anal sphincter defects of more than 120 degrees of the circumference, although a “high proportion” of the patients had pudendal neuropathy. The trial was not blinded. Of the 60 patients randomized to SNS, 54 (90%) had successful test stimulation and 53 decided to proceed with implant of the pulse generator. At baseline, the SNS group had an average of 9.5 incontinent episodes per week, and the controls had 9.2. Both groups had an average of 3.3 days per week with incontinence. At 12-month follow-up, episodes had decreased to 1 day per week with 3.1 episodes in the SNS group, but had not changed in the control group (mean 3.1 days per week) with 9.4 episodes. Complete continence was achieved in 22 of the 53 SNS patients (42%) and 13 patients (24%) improved by 75% to 99%. None of the patients had worsening of fecal continence. Adverse events included pain at implant site (6%), seroma (2%), and excessive tingling in the vaginal region (9%).

In 2005, Leroi et al in France published an industry-supported double-blind randomized crossover study.[15] Thirty-four patients had successful temporary percutaneous stimulation and underwent permanent implantation of an SNM device. Following a 1- to 3-month postimplantation period in which the device was turned on, patients had their device turned on for 1 month and off for 1 month, in random order. Twenty-four (71%) of randomized patients completed the study. There was a statistically significantly greater decrease in fecal incontinence episodes with the device turned on (p=0.03). However, there was also a large decrease in incontinent episodes for the placebo group. The median frequency of fecal incontinence episodes decreased by 90% when the device was in the on position; it decreased by 76% when the device was in the off position.

Prospective Noncomparative Studies

A key observational study was the 16-site multicenter FDA investigational device exemption study of SNS in 120 patients with fecal incontinence. Findings were initially reported by Wexner and colleagues in 2010.[16] To be included in the study, patients had to complain of chronic fecal incontinence with duration greater than 6 months or for more than 12 months after vaginal childbirth, defined as greater than 2 incontinent episodes on average per week. All patients had failed or were not candidates for more conservative treatments. Exclusion criteria included congenital anorectal malformation; previous rectal surgery, if performed within the last 12 months (or 24 months in case of cancer); defects of the external anal sphincter over 60 degrees; chronic inflammatory bowel disease; visible sequelae of pelvic radiation; active anal abscesses and fistulae; neurologic diseases such as clinically significant peripheral neuropathy or complete spinal-cord injury; and anatomic limitations preventing the successful placement of an electrode. A total of 285 patients were evaluated for potential enrollment; 133 were enrolled and underwent acute test stimulation, and 120 showed at least 50% improvement during the test phase and received a permanent stimulator. Thirty-four of the 120 patients exited the study for a variety of reasons both related (i.e., lack of efficacy in 6 and implant site infection or skin irritation in 5) and unrelated to the implant (i.e., death of a local principal investigator). Analysis based on the initial 133 patients showed a 66% success rate ($\geq$50% improvement), while analysis based on 106 patients who were considered completed cases at 12 months showed an 83% success rate. The success rate based on the 120 patients who received a permanently implanted stimulator would fall between these 2 figures. Of 106 cases included in the 12-month results, perfect continence (100% improvement) was reported in approximately 40%, while an additional 30% of patients achieved 75% or greater improvement in incontinent episodes. Success was lower in patients with an internal anal sphincter defect (65%[n=20]) compared with patients without a defect (87% [n=86]).

Three-year and 5-year findings were subsequently published. In 2011, Mellgren et al reported on the 120 patients who received a permanently implanted stimulator.[17] Mean length of follow-up was 3.1 years, and 83 (69%) completed at least part of the 3-year follow-up assessment. In ITT analysis using the last observation carried forward, 79% of patients experienced at least a 50% reduction in the number of incontinent episodes per week compared to baseline, and 74% experienced at least a 50% reduction in the number of incontinent days per week. In a per-protocol analysis at 3 years, 86% of patients experienced at least a 50% reduction in the number of incontinent episodes per week, and 78% experienced at least a 50% reduction in the number of incontinent days per week. By the 3-year follow-up, a total of 334 adverse events that were potentially device-related had been reported in 99 patients; 67% of these occurred within the first year. The most frequently reported adverse events among the 120 patients were implant site pain (28%), paresthesia (15%), implant site infection (10%), diarrhea (6%), and extremity pain (6%). Six infections required surgical intervention (5 device removals and 1 device replacement). In 2012, Hull and colleagues reported outcomes in 72 patients (60% of the 120 implanted patients) who had completed a 5-year follow-up visit.[18] Sixty-four (89%) of the patients who contributed bowel diary data at 5 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 5-year analysis.

A 2015 study by Altomare et al reported long-term outcome (minimum, 60-month follow-up; median, 84-month follow-up) in patients implanted with a sacral nerve stimulator for fecal incontinence.[19] 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 SNS 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.

Section Summary: Fecal Incontinence
The evidence base consists of longer-term results from two RCTs, observational including several with long-term follow-up and systematic reviews of RCTs and uncontrolled studies. Taken together, findings of these studies suggest that SNM/SNS improves outcomes when used for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy.

CONSTIPATION

Clinical Context and Therapy Purpose
The purpose of sacral nerve neuromodulation in patients with constipation who have failed conservative treatment is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does sacral nerve neuromodulation in patients with constipation who have failed conservative treatment improve net health outcomes?

The following **PICO** was used to select literature to inform this review.

Patients
The relevant population of interest is patients with constipation who have failed conservative treatment.

Intervention
The treatment being considered is sacral nerve neuromodulation, which is performed by a gastroenterologist in an outpatient clinical or surgical setting.

Comparators
The comparator of interest is continued conservative therapy, such as dietary modification or pharmacologic treatment.

Patients with refractory constipation are managed by gastroenterologists in an outpatient clinical setting.

Outcomes
The outcomes of interest are symptoms, morbid events, and treatment-related morbidity. Positive outcomes include regular bowel movements without complications from the device or implantation procedure.

Negative outcomes would be infection, bleeding, pain, and lead breakages, and lack of improvement in constipation.

Although no set standard for length of follow-up has been established, the existing literature evaluating sacral nerve neuromodulation for constipation has lengths of follow-up ranging from 3 weeks to 55 months.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Systematic Reviews
In the 2015 Cochrane review by Thaha et al on SNS for fecal incontinence and constipation in adults, 2 trials on SNM for constipation were included (Dinning et al [2015], and a crossover trial).[10] In 1 trial, the time with abdominal pain and bloating decreased during the "on" period from 79% to 33%. However, in the larger Dinning study, there was no improvement with SNM during the "on" period. Reviewers concluded: "SNS did not improve symptoms in patients with constipation."

In 2013, Thomas and colleagues published a systematic review of controlled and uncontrolled studies evaluating sacral nerve stimulation for treatment of chronic constipation.[20] The authors identified 11 case series and 2 blinded crossover studies. Sample sizes in the case series ranged from 4 to 68 patients implanted with a permanent SNS device; in 7 of the 11 studies, fewer than 25 patients underwent SNS implantation. Among the 2 crossover studies, one included 2 patients implanted with an SNS device. The other, a 2012 study by Knowles et al[21] evaluated temporary stimulation in only 14 patients. Patients were included if they were diagnosed with evacuatory dysfunction and rectal hyposensitivity and had failed maximal conservative treatment. They were randomized to 2 weeks of stimulation with the SNS device turned on and 2 weeks with the SNS 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 3 measures of rectal sensory thresholds. The study found a statistically significantly greater increase in rectal sensitivity with the device turned on in 2 of the 3 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 1,800 patients approached met the eligibility criteria and agreed to participate in the study.

Randomized Controlled Trials
In 2016, Zerbib et al reported on a double-blind crossover RCT of SNS in 36 women with refractory constipation.[22] Subjects were eligible if they had chronic constipation (>1 year), with 2 or fewer bowel movements per week, straining to evacuate with more than 25% of attempts, or sensation of incomplete evacuation with more than 25% of attempts, with lack of response to standard therapies. Thirty-six subjects meeting inclusion criteria underwent an initial peripheral nerve evaluation (PNE); those who had adequate symptom improvement to a predefined level were offered permanent SNS implant. After a 2- week washout, subjects were randomized to "on" or "off" for 8 weeks, followed by a 2-week washout, when the groups crossed over. Of the 36 patients enrolled, 20 responded and underwent randomization. Four were excluded (2 due to wound infection, 1 each due to withdrawal of consent and lack of

compliance). At 1-year follow-up, a positive response was observed in 12 of 20 and 11 of 20 patients after active and sham stimulation periods, respectively (p=0.746).

A larger randomized crossover trial was published by Dinning et al in 2015.[23] The study included patients aged 18 to 75 years with slow transit constipation. Potentially eligible patients completed a 3-week stool diary and, in order to continue participating, they needed to indicate in the diary that they had complete bowel movements less than 3 days per week for at least 2 of the 3 weeks. Patients with metabolic, neurogenic or endocrine disorders known to cause constipation were excluded. Fifty-seven met eligibility criteria and had temporary percutaneous nerve evaluation (PNE), and 55 underwent permanent implantation. In random order, patients received active stimulation (subsensory in phase 1, suprasensory in phase 2) or sham stimulation (device was on, but pulse width and frequency was set to 0). The primary outcome measure, determined by stool diaries, was a bowel movement with feelings of complete evacuation more than 2 days per week for at least 2 of 3 weeks; it was only assessed in phase 2. Compared with sham stimulation, 16 of 54 patients (29.6%) met the primary outcome during suprasensory 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 with suprastimulation versus sham stimulation and outcomes did not differ in the phase 1 comparison of subsensory versus sham stimulation.

Case Series

One of the larger case series was published in 2010 by Kamm et al.[24] This was a prospective study conducted at multiple sites in Europe. The study included 62 patients who had idiopathic chronic constipation lasting at least 1 year and had failed medical and behavioral treatments. Constipation was defined as at least one of the following: fewer than 2 bowel movements per week, straining to evacuate in at least 25% of attempts or a sensation of incomplete evacuation on at least 25% of occasions. Forty-five of the 62 (73%) met criteria for permanent implantation during the 3-week trial period. Criteria included an increase in evacuation frequency to at least 3 per week, or a 50% reduction in either frequency of straining during evacuation or in episodes with sensation of incomplete evacuation. 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 1 serious event). The serious adverse events included a deep postoperative infection (n=2), superficial erosion of lead through the skin (n=1), persistent postoperative pain at the site of implantation (n=2), conditions leading to lead revision (n=4), and device failure (n=2). The study has been criticized for including a large number of patients who had more than 2 bowel movements per week at study entry.

An additional study, published by Maeda et al in 2010, focused on reporting adverse events.[25] The study was a chart review and included 38 patients with constipation who received permanent SNS after a successful trial period. At the time that charts were reviewed, 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 2 (range 1-9) events per patient were reported; 26 of 58 events (45%) were reported in the first 6 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.

Section Summary: Constipation
Four randomized crossover studies are available; 2 had very small sample sizes and the third did not find a significant difference in outcomes when active SNS was compared with sham stimulation. There are also several, mainly small, case series. This represents insufficient evidence to permit scientific conclusions about the effect of SNM/SNS on health outcomes in patients with constipation.

CHRONIC PELVIC PAIN

Clinical Context and Therapy Purpose
The purpose of sacral nerve neuromodulation in patients with chronic pelvic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does sacral nerve neuromodulation in patients with chronic pelvic pain improve net health outcomes?

The following **PICO** was used to select literature to inform this review.

Patients
The relevant population of interest is patients with chronic pelvic pain.

Intervention
The treatment being considered is sacral nerve neuromodulation. The type of physician who performs the procedure would depend on where the suspected source of the pain lies; the procedure could be performed by a gastroenterologist, gynecologist, or urologist in an outpatient clinical or surgical setting.

Comparators
The comparator of interest is continued conservative therapy, such as cognitive behavioral therapy or pharmacologic treatment.
Patients with chronic pelvic pain are managed by gastroenterologists, gynecologists, or urologists in an outpatient clinical setting.

Outcomes
The outcomes of interest are symptoms, morbid events, and treatment-related morbidity. Positive outcomes include relief from chronic pelvic pain without complications from the device or implantation procedure.

Negative outcomes would be infection, bleeding, pain, and lead breakages, and lack of improvement in constipation.

Although no set standard for length of follow-up has been established, the existing literature evaluating sacral nerve neuromodulation for chronic pelvic pain has a length of follow-up of 1 year.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

A 2013 systematic review of studies (Tirlapur et al) on nerve stimulation for chronic pelvic pain did not identify any RCTs on SNS for treatment of chronic pelvic pain or bladder pain.[26] The published evidence is limited to case series. For example, in 2012 Martelluci et al reported on 27 patients with chronic pelvic pain (at least 6 months) who underwent testing for SNM implantation.[27] 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 analog scale was 8.1 before implantation and 2.1 at the 6- and 12-month follow-ups. An earlier study by Siegel et al reported on 10 patients and stated that 9 of the 10 experienced a decrease in pain with SNS stimulation.[28]

Section Summary: Chronic Pelvic Pain
Data from several small case series with heterogenous patients represents insufficient evidence about the effect of SNM/SNS on health outcomes in patients with chronic pelvic pain. RCTs are needed, especially with sham controls, reporting pain as the primary outcome.

Trial Stimulation Techniques
As described in the Background section, there are 2 types of trial stimulation before permanent implantation of a neuromodulation device. These are percutaneous nerve evaluation (PNE) and stage 1 (lead implantation) of a 2-stage surgical procedure. The PNE was the initial method of trial stimulation and has been the standard of care prior to permanent implantation of the device. In review articles such as Baxter and Kim 2010, lead migration was described as a potential problem with the PNE technique, but no studies were identified that quantified the rate of lead migration in large numbers of patients.[29] The 2-stage surgical procedure is an alternate trial stimulation modality.

Comparative rates of lead migration and rates of progressing to permanent implantation are useful outcomes in that there may be reduced sensitivity of the PNE test due to lead dislodgement. However, due to the potential placebo effect of testing, it is also important to compare the long-term efficacy of SNM after these 2 trial stimulation techniques. In addition, it would be useful to have data on the optimal approach to using the 2-stage surgical procedure. As mentioned previously in the Background section, the 2-stage surgical procedure has been used in various ways including instead of PNE, for patients who failed PNE, for patients with an inconclusive PNE, and for patients who had a successful PNE to further refine patient selection.

No RCTs were identified that evaluated long-term health outcomes (e.g., reduction in incontinence symptoms) after trial stimulation with PNE versus stage-1 lead implantation. There are limited data on the issue of rates of failure after SNM in patients selected using the 2-stage test. Leong et al, in a single-center prospective study published in 2011, evaluated 100 urge incontinence patients with both PNE and the first stage of the 2-stage technique (i.e., patients served as their own controls).[30] Patients were first screened with the PNE and,

afterwards, with lead implantation. Response to testing was based on diary data for 3 consecutive days after receiving each type of lead. In the test phase, 47 patients (47%) had a positive response to PNE, and 69 (69%) had a positive response to the first-stage lead placement test. All patients who responded to PNE also responded to stage-1 testing. The 69 patients who responded to stage-1 testing underwent implantation. They were then followed for a mean of 26 months, and 2 patients (3% of those with a positive test) had failed therapy. Although this study showed a low rate of failure, only 22 individuals had a successful test with the stage-1 technique but not with PNE. This is a small number of patients on which to base conclusions about the comparative efficacy of the 2 techniques. In addition, the order of testing could have impacted findings. All patients had PNE testing prior to first-stage lead implantation and could have been biased by their first test. Stronger study designs would be to randomize the order of testing or to randomize patients to receive one type of testing or the other.

In 2002, Scheepens et al conducted an analysis of 15 patients with urinary incontinence or retention who had a good initial response to PNE but then failed PNE in the longer term (i.e., days 4-7 of testing).[31] These 15 patients underwent stage 1 of the 2-stage technique. One patient failed the first stage and was explanted. Of the remaining 14 patients, 2 were explanted later due to lack of efficacy of sacral neuromodulation. The other 12 patients were followed for a mean of 4.9 years and voiding diary data showed improvement in nearly all incontinence symptoms. There was a low failure rate after stage-1 testing, but this is a small sample size, and stage-1 testing was not compared to another trial stimulation method, (e.g., PNE.)

In 2010, Marcelissen et al published findings in 92 patients with urinary symptoms who underwent trial evaluation for SNM treatment.[24] Patients initially underwent PNE (n=76) or stage-1 surgery (n=16). Patients who had a negative PNE (n=41) then underwent stage-1 evaluation. A total of 11 of 16 (63%) patients had a positive initial stage-1 test and were implanted with a SNM device. Thirty-five of 76 (46%) patients had a positive initial PNE test and underwent permanent implantation. There were 41 patients (54% of those undergoing PNE) who had a negative test and then had stage-1 surgical evaluation. Eighteen of 41 (44%) had a positive stage-1 test and underwent implantation. Altogether there were 64 patients who underwent implantation of an SNM device. Mean follow-up was 51 months. Thirty-eight of 64 patients (59%) implanted experienced clinical success at last follow-up, defined as greater than 50% improvement in symptoms reported in a voiding diary. Clinical success rate was not reported separately by trial stimulation method.

Several studies, e.g., Borawski et al (2006)[33] and Bannowsky et al (2008),[34] compared response rates during the test phase in patients with urinary incontinence symptoms and found higher response rates with the stage-1 test than with PNE. In these studies, more people who received the stage-1 test went on to undergo implantation. The Borawski et al study was an RCT with 30 patients (13 received PNE and 17 received the stage-1 test). The Bannowsky et al study was not randomized; 42 patients received a PNE, and 11 patients received a stage-1 test. Neither study, however, followed patients once they had a device implanted so they do not provide data on the relative success rate of SNM after these 2 test procedures. With this type of study (i.e., without follow-up after implantation), it is not possible to conclude whether the 2-stage procedure reduced false-negatives (i.e., selected more people who might benefit) or increased false-negatives (i.e., selected more people who might go on to fail).

No published studies were identified that compare different trial stimulation techniques in patients with non-urinary conditions (e.g., fecal incontinence.)

SUMMARY OF EVIDENCE

For individuals with urinary incontinence who have failed conservative treatment who receive sacral nerve neuromodulation (SNM), the evidence includes randomized controlled trials (RCTs), systematic reviews, and case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Results from the RCTs and case series with long-term follow-up have suggested that SNM reduces symptoms of urge incontinence, urgency-frequency syndrome, nonobstructive urinary retention, and overactive bladder in selected patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with fecal incontinence who have failed conservative treatment who receive SNM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Although relatively small, the available trials had a low risk of bias and demonstrated improvements in incontinence relative to alternatives. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with constipation who have failed conservative treatment who receive SNM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The available trials have not consistently reported improvements in outcomes with SNM. Additional studies are needed to demonstrate the health benefits of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic pelvic pain who receive SNM, the evidence is limited. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The evidence is insufficient to determine remains insufficient to evaluate the effects of this technology on health outcomes.

SUPPLEMENTAL INFORMATION

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03139734	Sacral neuromodulation for pelvic pain associated with endometriosis	50	May 2022
NCT02434874	Sacral nerve stimulation to treat urgency urinary incontinence with wireless neuromodulation	60	Dec 2022
NCT03261622	Sacral nerve stimulation for fecal incontinence-placebo or clinical effectiveness (SNS)	75	Nov 2020
NCT02961465	Effectiveness and safety of sacral neuromodulation in patients with idiopathic slow-transit constipation	61	Aug 2021

NCT: national clinical trial

Clinical Input Received through Physician Medical Societies and Academic Medical Centers

In response to requests, BCBSA received input through 4 Physician Specialty Societies and 2 Academic Medical Centers while this policy was under review in 2012. While the various Physician Specialty Societies and Academic Medical Centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the Physician Specialty Societies or Academic Medical Centers, unless otherwise noted. Reviewers from 2 Specialty Societies and 2 Academic Medical Centers provided opinions regarding the possible medical necessity of implantable leads for test stimulation, as part of a 2-stage process for device implantation. All 4 respondents supported the use of implantable leads for test stimulation as an alternative to percutaneous test stimulation, for patients who failed percutaneous test stimulation and/or for patients with inconclusive percutaneous test stimulation. Reasons for support included a longer period of interrupted treatment with stage-1 stimulation due to less lead migration and a higher rate of positive tests compared to percutaneous test stimulation.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Urological Association (AUA)

In 2014, the American Urological Association issued updated guidelines on diagnosis and treatment of overactive bladder.[35] The guidelines stated that sacral neuromodulation may be offered as a third-line treatment in carefully selected patients with severe refractory symptoms or in those who are not candidates for second-line therapy (e.g., oral anti-muscarinics, oral β3-adrenoceptor agonists, transdermal oxybutynin) and are willing to undergo surgery.

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence issued a guidance on management of fecal incontinence in 2007. It recommended: “a trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate…. All individuals should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. People with faecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success.”[36]

American College of Gastroenterology (ACG)

A 2014 ACG guideline on fecal incontinence states that “sacral nerve stimulation should be considered in patients with fecal incontinence who does not respond to conservative therapy (strong recommendation, moderate quality of evidence).

American College of Obstetricians and Gynecologists (ACOG)

- A 2005 position statement considered SNS to be beneficial for treating chronic voiding dysfunction.[38]
- A 2004 position statement recommended that SNS be considered as a treatment option for chronic pelvic pain. According to the ACOG website, accessed in March 2014, the practice bulletin on chronic pelvic pain is no longer maintained.[39]

Government Regulations

National Coverage Determination, Publication 100-3.
Effective January 1, 2002, the Centers for Medicare & Medicaid Services covers SNS for the "treatment of urinary urge incontinence, urgency-frequency syndrome and urinary retention.[40] SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered."

"The following limitations for coverage apply to all three indications:

- Patients must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be appropriate surgical candidates such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) that are associated with secondary manifestations of the above three indications are excluded.
- Patients must have had successful test stimulation in order to support subsequent implantation. Before patients are eligible for permanent implantation, they must demonstrate a 50% or greater improvement through test stimulation.
- Improvement is measured through voiding diaries. Patients must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated."

Local:

There is no WPS LCD on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Radiofrequency Micro-Remodeling for Stress Incontinence
- Transanal Radiofrequency for Fecal Incontinence
- Magnetic Pelvic Floor Stimulation for Urinary Incontinence
- Psychophysiological Therapy for Treatment of Nocturnal Enuresis
- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2021, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
2/6/03	2/6/03	2/14/03	Joint medical policy established
9/5/04	9/5/04	8/27/04	Routine maintenance
1/1/07	11/1/06	10/23/06	Routine maintenance, coding update
3/1/09	12/9/08	12/28/08	Routine maintenance
9/1/12	6/12/12	6/15/12	Added sacral nerve stimulation for fecal incontinence. Reformatted policy to mirror BCBSA policy. Added references. Changed title from "Sacral Nerve Stimulation for Urinary Dysfunction" to "Sacral Nerve Neuromodulation/Stimulation"
11/1/13	8/20/13	9/3/13	Routine maintenance The following revisions were made to the criteria: Length of successful percutaneous test stimulation changed from at least 2 weeks to at least 1 week. Fecal incontinence separated into 2 statements; 1 on trial stimulation and 1 on permanent implantation. Edits made so that criteria for fecal and urinary incontinence are similar, when applicable
3/1/15	12/9/14	12/29/14	Routine maintenance. Rationale and references updated.
7/1/16	4/19/16	4/19/16	Routine maintenance. No change in policy status.
7/1/17	4/18/17	4/18/17	Routine maintenance. In order to mirror BCBSA, changed inclusionary guidelines for temporary stimulator to read, "A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours." Previously read "at least one week." Added references and updated rationale. No change in policy status.

7/1/18	4/17/18	4/17/18	Routine policy maintenance. Updated clinical trials section. No change in policy status.
5/19/19	2/19/19		Routine policy maintenance. Nomenclature update for code 95970.
5/1/20	2/18/20		Routine policy maintenance. No change in policy status.
5/1/21	2/16/21		Routine policy maintenance. No change in policy status. Codes 64590 and 64595 removed as they relate to gastric neurostimulation not sacral.

Next Review Date: 1st Qtr. 2022

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 5/8/01	Revised: N/A
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SACRAL NERVE NEUROMODULATION/STIMULATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.