7.01.69	Sacral Nerve Neuromodulation/Stimulation	
Section 7.0 Surgery	**Effective Date** August 29, 2014	
Subsection	**Original Policy Date** June 10, 1998	**Next Review Date** August 2015

Description

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.

Note: Sacral nerve neuromodulation/stimulation should be distinguished from pelvic floor stimulation and sacral anterior root stimulation.

Related Policies

- Biofeedback
- Neuromuscular, Functional, and Threshold Electrical Stimulation
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Urinary Incontinence Outpatient Treatment

Policy

Urinary Incontinence and Nonobstructive Retention

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in patients who meet **all** of the following criteria:

- There is a diagnosis of at least **one** of the following:
  - Urge incontinence
  - Urgency-frequency syndrome
  - Nonobstructive urinary retention
  - Overactive bladder
- There is documented failure or intolerance to at least 2 conventional conservative therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy)
- The patient is an appropriate surgical candidate

- Incontinence is not related to a neurologic condition

Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in patients who meet **all** of the following criteria:

- **All** of the criteria for percutaneous nerve stimulation or a temporarily implanted lead are met (listed above)
- A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 1 week

Other urinary/voiding applications of sacral nerve neuromodulation are considered **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

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in patients who meet **all** of the following criteria:

- 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
- 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)
- The patient is an appropriate surgical candidate
- 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
- Incontinence is not related to a neurologic condition
- 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

Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in patients who meet **all** of the following criteria:

- **All** of the criteria for percutaneous nerve stimulation or a temporarily implanted lead are met (listed above)
- A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 1 week

Sacral nerve neuromodulation is considered **investigational** in the treatment of **either** of the following:

- Chronic constipation
- Chronic pelvic pain

Policy Guidelines

The International Continence Society states that overactive bladder syndrome (OAB) "is defined as urinary urgency, usually with urinary frequency and nocturia, with or without urgency urinary incontinence." Retrieved on May 21, 2014 from: http://wiki.ics.org/Overactive+Bladder

Sacral nerve neuromodulation involves several steps that are identified by the following CPT and HCPCS codes.

1. Peripheral nerve evaluation to determine candidacy for permanent implantation would be reported using the following codes:

- HCPCS codes:
  - **A4290**: Sacral nerve stimulation test lead, each
  - **E1399**: Bulk leads, needles, and cables
  - **E0745**: Stimulator electronic shock unit
- CPT code:
  - **64561**: Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
- ICD-9-CM procedure code:
  - **04.92**: Implantation or replacement of peripheral neurostimulator lead(s)

2. Open implantation of the electrode array whether as the first stage of the 2-stage implantation procedure, or as the final implantation of the electrode array after a positive percutaneous test, would be reported using the following codes:

- HCPCS code:
  - **L8680**: Implantable neurostimulator electrode each
- CPT code:
  - **64581**: Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
- ICD-9-CM procedure codes
  - **04.92**: Implantation or replacement of peripheral neurostimulator lead(s)

3. Open implantation of the neurostimulator pulse generator would be reported using the following codes:

- HCPCS code:
  - **L8685, L8686, L8687** or **L8688**: Implantable neurostimulator pulse generator
- CPT code
  - **64590**: Incision and subcutaneous placement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
- ICD-9-CM procedure codes
  - **86.94**: Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable

4. Some patients will require analysis and reprogramming of the device once implanted. The following CPT codes may be used. A site of service differential may apply.

- CPT codes:
    - Electronic analysis of implanted neurostimulator pulse generator system:
        - **95970**: Without reprogramming
        - **95972**: With intraoperative or subsequent programming, first hour
    - **95973**: As above, but each additional 30 minutes after first hour

5. Some patients may require revision or removal of the implanted electrodes or pulse stimulator. The following CPT codes may be used.

- CPT codes:
    - **64585**: Revision or removal or peripheral neurostimulator electrode array
    - **64595**: Revision or removal of implanted peripheral neurostimulator pulse generator or receiver

Note: HCPCS code **L8680** is reported with one unit for each contact point on the implanted lead.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

Background

Treatment using sacral nerve neuromodulation (SNM), also known as indirect sacral nerve stimulation (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. 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.

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 treatment. 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 to 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 to 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.

Note: This policy does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Pelvic floor stimulation is addressed separately in Blue Shield of California Medical Policy: Urinary Incontinence Outpatient Treatment. 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 VOCARE® sacral nerve stimulator, which is intended for patients with complete spinal cord injury and neurogenic bladder.

This policy was originally based on two Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessments from 1998 and 2000, which focused on sacral nerve neuromodulation (SNM) for urge incontinence and urinary urgency/frequency, respectively.

Urinary Incontinence

Three randomized controlled trials (RCTs) on SNM for urinary incontinence have been conducted. The larger study was sponsored by Medtronic (1999) and submitted to the FDA as part of the approval process. Findings have not otherwise been published. Based on this RCT, the 1998 TEC Assessment concluded that SNM reduced urge incontinence compared with control patients. This well-designed trial, using standardized clinical and functional status outcomes measurements, 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 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 the above 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 with a control group, patients with implants reported significant improvements in quality of life (QOL), as evaluated by the Short-Form 36-Item Health Survey.

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

In 2014, a third RCT was published by Siegel et al.; this was an industry-sponsored FDA-mandated postapproval study. This study compared SNM using a 2-stage surgical procedure to standard medical therapy. 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. 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).

In addition to the RCTs, case series have been published in recent years. For example, a 2011 series by Groen et al. in The Netherlands reported the longest follow-up. A total of 60 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 of 60 (87%) 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 of 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 re-operations 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. The study 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.

A 2009 Cochrane review by Herbison and Arnold evaluated the literature on implanted devices for urinary storage and voiding dysfunction in adults. The authors stated that, in spite of methodologic problems (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." They 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.

Section Summary

Data from RCTs and case series with long-term follow-up suggest that SNM reduces symptoms of urge incontinence, urgency-frequency syndrome, nonobstructive urinary retention, and overactive bladder in selected patients.

Fecal Incontinence

In 2013, Thin et al. published a systematic review of randomized trials and observational studies on SNM for treating fecal incontinence. 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 2 of the studies were RCTs (the Tjandra et al. and Leroi et al. studies, described next) and 50 were prospective case series. Data from 2 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.

Previously, in 2011, Tan et al. published a meta-analysis of studies of SNM for treating fecal incontinence. They identified a total of 34 studies that reported on at least 1 of their outcomes of interest and clearly documented how many patients underwent temporary and permanent SNM. Only 1 of these studies was an RCT (Tjandra et al.). In the 34 studies, a total of 944 patients underwent temporary sacral nerve stimulation (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 with 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 with conservative therapy (weighted mean difference: -10.57; 95% CI: -11.89 to -9.24; p<0.001).

The 2 RCTs are described briefly next:

In 2008, Tjandra et al. published an RCT with 120 patients with severe fecal incontinence. Patients were randomly assigned to receive SNS 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 study 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. 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. A total of 24 patients (71%) 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.

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 et al. in 2010. 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, 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 (≥ 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. Mean length of follow-up was 3.1 years, and 83 (69%) completed at least part of the 3-year follow-up assessment. In an intention-to-treat analysis using the last observation carried forward, 79% of patients experienced at least a 50% reduction in the number of incontinent episodes per week compared with baseline, and 74% experienced at least a 50% reduction in the number of incontinent days per week. In a per-protocol analysis at 3 years, 86% of patients experienced at least a 50% reduction in the number of incontinent episodes per week, and 78% experienced at least a 50% reduction in the number of incontinent days per week. By the 3-year follow-up, 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 2013, Hull et al. reported outcomes in 72 patients (60% of the 120 implanted patients) who had completed a 5-year follow-up visit. 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.

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. The authors identified 94 articles. Most studies addressed fecal incontinence. A combined analysis of data from 31 studies on SNS 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 of 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 of 1,025 patients). Twenty-five of the 40 infections (63%) led to explantation of the device.

Section Summary

The evidence base consists of 2 RCTs, observational studies 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

In 2013, Thomas et al. published a systematic review of controlled and uncontrolled studies evaluating SNS for treatment of chronic constipation. 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. 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.

One of the larger case series was published in 2010 by Kamm et al. 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 1 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 ($p=0.001$). 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. 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

Only 2 small controlled studies are available, both crossover studies; 1 had only 2 patients and the other had methodologic limitations. In addition, there are 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

A 2013 systematic review by Tirlapur et al. of studies on nerve stimulation for chronic pelvic pain did not identify any RCTs on SNS for treatment of chronic pelvic pain or bladder pain. 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. 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 was 8.1 before implantation and 2.1 at the 6- and 12-month follow-ups. An earlier study by Siegel et al. (2001) reported on 10 patients and stated that 9 of the 10 experienced a decrease in pain with SNS stimulation.

Section Summary

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.

Trial Stimulation Techniques

As described in the previous 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 before 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. 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). 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 subjects 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 before 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 1 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). 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 SNM. 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 with 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. 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.

Two studies, Borawski et al. (2006) and Bannowsky et al. (2008) compared the response rates during the test phase in patients with urinary incontinence symptoms and found higher rates of response 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 nonurinary conditions (e.g., fecal incontinence).

Ongoing and Unpublished Clinical Trials

InSite for Over Active Bladder (InSite - OAB) (NCT00547378): This randomized open-label trial is comparing the safety and efficacy of sacral neuromodulation using the InterStim device to standard medical therapy in patients with overactive bladder who failed at least 1 previous medication. Patients will be followed for 5 years. The primary efficacy outcomes, change in overactive bladder symptoms at 6 months, were published in 2014 by Siegel et al. The primary safety outcome, safety of the tined lead, will be reported at 5 years. The estimated study completion date is November 2016. Sponsored by MedtronicNeuro.

Refractory Overactive Bladder: Sacral NEuromodulation v. BoTulinum Toxin Assessment (ROSETTA) (NCT01502956): This randomized, open-label trial is comparing the safety and efficacy of sacral neuromodulation (InterStim) with injections of botulinum toxin A for the treatment of refractory urge urinary incontinence. Patients will be followed for 24 months; primary outcomes are changes in urge incontinence symptoms at 6 months. The estimated study completion date is December 2016. Sponsored by NICHD Pelvic Floor Disorders Network.

Summary

There is sufficient evidence to conclude that sacral nerve neuromodulation (SNM)/stimulation (SNS) is effective and safe in selected patients with urge incontinence, urgency-frequency, and nonobstructive urinary retention. In addition, the evidence is considered sufficient for SNM to be an option for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy. Therefore, SNM may be considered medically necessary under specific conditions in the above patients. Not all patients will benefit, and the adverse event rate for this procedure is high. Patients should therefore be provided with adequate information to make an informed choice regarding the potential risks and benefits of this procedure.

Limited evidence reports that more patients have a positive stimulation trial when stage-1 surgery is used compared with percutaneous nerve evaluation and that most patients with a positive stage-1 test experience a reduction in symptoms after permanent implantation. This evidence does not determine with certainty that health outcomes are improved with the stage-1 trial stimulation. However, due to the available evidence, as well as strong clinical support for surgical lead placement as an alternative to percutaneous test stimulation, surgical lead placement may be considered medically necessary for otherwise eligible patients.

The literature on SNS for constipation or chronic pelvic pain remains insufficient to evaluate the effect of this technology on health outcomes; thus SNM is considered investigational for these indications.

Practice Guidelines and Position Statements

The 2007 National Institute for Health and Care Excellence (NICE) guidance on management of fecal incontinence 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.

The 2004 American College of Gastroenterology (ACG) practice guideline by Rao, on the diagnosis and management of fecal incontinence found limited evidence in favor of SNS. The ACG concluded that the precise indication for SNS, its comorbidity, its long-term outcome, and efficacy remain to be defined.

A 2005 American College of Obstetricians and Gynecologists (ACOG) position statement on urinary incontinence in women considered SNS to be beneficial for treating chronic voiding dysfunction. A 2004 ACOG 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.

Medicare National Coverage

Effective January 1, 2002, SNS is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. 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.

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Documentation Required for Clinical Review

- History and physical and/or consultation notes including:
  - Diagnosis of type of incontinence and frequency
  - Prior trial of conservative therapies and patient response
  - Documented trial stimulation period demonstrating at least 50% improvement in symptoms (for permanent implant)
  - Operative report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria

are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	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 system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
	95972	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
	95973	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling,

		impedance and patient compliance measurements); complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (Li
HCPC	A4290	Sacral nerve stimulation test lead, each
	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1787	Patient programmer, neurostimulator
	C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
	C1897	Lead, neurostimulator test kit (implantable)
	E0745	Neuromuscular stimulator, electronic shock unit
	E1399	Durable medical equipment, miscellaneous
	L8680	Implantable neurostimulator electrode, each
	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
ICD-9 Procedure	04.92	Implantation or replacement of peripheral neurostimulator lead(s)
	86.94	Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable
ICD-10 Procedure	***For dates of service on or after 10/01/2015***	
	01HY0MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
	01HY3MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach
	01HY4MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Endoscopic Approach
	01PY0MZ	Removal of Neurostimulator Lead from Peripheral Nerve, Open Approach
	01PY3MZ	Removal of Neurostimulator Lead from Peripheral Nerve, Percutaneous Approach

	01PY4MZ	Removal of Neurostimulator Lead from Peripheral Nerve, Percutaneous Endoscopic Approach
	01WY0MZ	Revision of Neurostimulator Lead in Peripheral Nerve, Open Approach
	01WY3MZ	Revision of Neurostimulator Lead in Peripheral Nerve, Percutaneous Approach
	01WY4MZ	Revision of Neurostimulator Lead in Peripheral Nerve, Percutaneous Endoscopic Approach
	0JH60M6	Insertion of Single Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH60M7	Insertion of Dual Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH60M8	Insertion of Single Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH60M9	Insertion of Dual Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH63M6	Insertion of Single Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH63M7	Insertion of Dual Array Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH63M8	Insertion of Single Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH63M9	Insertion of Dual Array Rechargeable Stimulator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH80M6	Insertion of Single Array Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH80M7	Insertion of Dual Array Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH80M8	Insertion of Single Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH80M9	Insertion of Dual Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH83M6	Insertion of Single Array Stimulator Generator into

		Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH83M7	Insertion of Dual Array Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH83M8	Insertion of Single Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH83M9	Insertion of Dual Array Rechargeable Stimulator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JPT0MZ	Removal of Stimulator Generator from Trunk Subcutaneous Tissue and Fascia, Open Approach
	0JPT3MZ	Removal of Stimulator Generator from Trunk Subcutaneous Tissue and Fascia, Percutaneous Approach
ICD-9 Diagnosis	787.60 - 787.63	Incontinence of feces, code range
	788.20 - 788.29	Retention of urine, code range
	788.30 - 788.39	Urinary incontinence, code range
ICD-10 Diagnosis	***For dates of service on or after 10/01/2015***	
	N39.41	Urge incontinence
	R15.0 – R15.9	Fecal incontinence, code range
	R33.0 - R33.9	Retention of urine, code range
	R35.0	Frequency of micturition

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
6/10/1998	New Policy Adoption	Medical Policy Committee
10/20/1999	Policy Review	Medical Policy Committee
1/11/2008	Policy Revision Title change. Prior policy title: Implantable Unilateral Sacral Nerve Stimulation for Urinary Incontinence. Code Revision.	Medical Policy Committee
9/25/2009	Policy Title Revision, criteria revised	Medical Policy Committee
10/29/2010	Coding Update	Administrative Review
4/1/2011	Policy revision with position	Medical Policy Committee

	change	
8/29/2014	Policy revision with position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.