



BlueCross BlueShield
of Alabama

Name of Policy:

Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction

Policy #: 159
Category: Surgery

Latest Review Date: July 2014
Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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

Treatment using 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. 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.

Prior to 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 several days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. Patients then keep track of voiding symptoms while the temporary device is functioning. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in incontinence frequency, they are deemed eligible for the permanent device. According to data from the manufacturer, approximately 63% of patients have a successful peripheral nerve evaluation and are thus candidates for the permanent SNM.

The second type of testing is a two-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 one–two seconds.

Policy:

Effective for dates of service on or after September 9, 2014:

Sacral nerve neuromodulation meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the **treatment of urge incontinence, urgency-frequency syndrome, non-obstructive urinary retention and overactive bladder in patients when all of the following criteria are met:**

- Documented failure or intolerance to conventional conservative therapy (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy); AND
- The patient is an appropriate surgical candidate; AND
- A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms over a period of at least one week (**effective on or after April 11, 2013**), was performed; AND
- Condition is not related to a neurologic condition.

Sacral nerve neuromodulation meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the **treatment of fecal incontinence when all of the following criteria are met:**

- Chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than six months or for more than 12 months after vaginal childbirth; AND
- 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, performed more than 12 months [or 24 months in case of cancer] previously); AND
- The patient is an appropriate surgical candidate; AND
- A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms over a period of at least two weeks, was performed; AND
- 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; AND

- Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Temporary or permanent sacral nerve neuromodulation/ stimulation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for treatment of chronic voiding dysfunction not described above, stress incontinence or urge incontinence due to a neurologic conditions (e.g., detrusor hyperreflexia, multiple sclerosis, or spinal cord injury), chronic constipation or chronic pelvic pain.

Permanent implantation of the sacral nerve stimulator does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients with neurological conditions such as spinal cord injury, diabetic neuropathy or multiple sclerosis.

Effective for dates of service on or after December 1, 2010 and prior to September 9, 2014:
Sacral nerve neuromodulation meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the **treatment of urge incontinence, urgency-frequency syndrome, non-obstructive urinary retention in patients when all of the following criteria are met:**

- Documented failure or intolerance to conventional conservative therapy (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy); AND
- The patient is an appropriate surgical candidate; AND
- A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms over a period of at least one week (**effective on or after April 11, 2013**), was performed; AND
- Condition is not related to a neurologic condition.

Sacral nerve neuromodulation meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the **treatment of fecal incontinence when all of the following criteria are met:**

- Chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than six months or for more than 12 months after vaginal childbirth; AND
- 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, performed more than 12 months [or 24 months in case of cancer] previously); AND
- The patient is an appropriate surgical candidate; AND
- A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms over a period of at least two weeks, was performed; AND
- 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; AND

- Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Temporary or permanent sacral nerve neuromodulation/ stimulation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for treatment of chronic voiding dysfunction not described above, stress incontinence or urge incontinence due to a neurologic conditions (e.g., detrusor hyperreflexia, multiple sclerosis, or spinal cord injury), chronic constipation or chronic pelvic pain.

Permanent implantation of the sacral nerve stimulator does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients with neurological conditions such as spinal cord injury, diabetic neuropathy or multiple sclerosis.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was originally based on TEC Assessments from 1998 and 2000, which focused on sacral nerve neuromodulation (SNM) for urge incontinence and urinary urgency/frequency, respectively. The literature has been periodically updated using the MEDLINE database. The most recent literature review was performed through March 5, 2014.

Urinary Incontinence

Three randomized controlled trials (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. 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 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 six 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. At six 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 eight voids per day and/or at least two involuntary leaking episodes in 72 hours) and a failed trial of at least one anticholinergic or antimuscarinic medication. In addition, there needed to be at least one such medication that had not yet been attempted. Patients with neurologic diseases and with primary stress incontinence were excluded. A total of 70 patients were allocated to SNM and 77 to standard medical therapy. Of the 70 patients in the SNM group, 11 elected not to receive test stimulation with the tined lead and eight received the lead but did not receive a full system implant due to lack of response to a 14-day test stimulation period (response was defined as at least a 50% reduction in average leaks and/or voids). Patients in the medical treatment group tried the next recommended medication or restarted a discontinued medication. In an intention-to-treat analysis, the therapeutic success rate at six months was 61% in the SNM group and 42% in the standard medical treatment group; the difference between groups was statistically significant (p=0.02). QOL at six months was a secondary outcome. Several validated QOL scales were used, and all favored the SNM group compared with the standard medical treatment group (p<0.002 for all comparisons).

In 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 five years of follow-up after SNM for refractory idiopathic urge urinary incontinence. Success was defined as at least a 50% decrease in the number of incontinent episodes or pads used per day. The success rate was 52 of 60 (87%) at one month and gradually decreased to 37 (62%) at five years. The number of women who were completely continent was 15 (25%) at one month and nine (15%) at five years. At the five-year follow-up, SNM was still used by 48/60 (80%) women. A total of 57 adverse events were reported in 32 of 60 (53%)

patients. The most frequent adverse events were hardware-related or pain or discomfort. There were a total of 23 reoperations in 15 patients. In most cases, pain problems were managed conservatively.

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 to 84), 67 patients (30%) had experienced adverse events that required either lead or implantable pulse generator revisions. Complications included pain (3%), device malfunction secondary to trauma (9%), infection (4%), postoperative hematoma (2%), and lead migration (6%). In addition, 5% of patients underwent elective removal, 4% had device removal due to lack of efficacy, and 2% required removal due to battery expiration. At the last follow-up, 172 patients (85%) had functional implanted units.

A 2009 Cochrane review 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.

In 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 ten patients, having a clear follow-up interval and reporting the success rate of therapy based on a 50% or greater improvement in fecal incontinence episodes. Only two of the studies were RCTs (the Tjandra et al and Leroi et al studies, described next) and 50 were prospective case series. Data from two studies with long-term follow-up could be pooled to calculate median success rates using an intention-to-treat analysis. These median success rates were 63% in the short term (no more than 12 months’ follow-up), 58% in the medium term (12-36 months), and 54% in the long term (>36 months). The per-protocol short-, medium-, and long-term success rates were 79%, 80%, and 84%, respectively.

Previously, in 2011, Tan et al published a meta-analysis of studies SNM for treating fecal incontinence. 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). 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 two 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 two 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 dietitians. 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 one 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 one- to three-month postimplantation period in which the device was turned on, patients had their device turned on for one month and off for one month, in random order. A total of 24 patients (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.

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 six months or for more than 12 months after vaginal childbirth, defined as greater than two 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 six, implant site infection or skin irritation in five) 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 two 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 five-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 three-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 three 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 three-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 (five device removals and one device replacement). In 2012, Hull et al reported outcomes in 72 patients (60% of the 120 implanted patients) who had completed a five-year follow-up visit. Sixty-four (89%) of the patients who contributed bowel diary data at five years had at least a 50% improvement from baseline in weekly incontinent episodes, and 26 of the 72 patients (36%) had achieved total continence. It is uncertain whether outcomes differed in the 40% of patients who were missing from the five-year analysis.

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 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 explantation of the device and reprogramming. The second most common adverse event was infection, with a pooled rate of 4% (40/1025 patients). Twenty-five of the 40 infections (63%) led to explantation of the device.

The evidence base consists of two 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 two blinded crossover studies. Sample sizes in the case series ranged from four to 68 patients implanted with a permanent SNS device; in seven of the eleven studies, fewer than 25 patients underwent SNS implantation. Among the two crossover studies, one included two 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 two weeks of stimulation with the SNS device turned on and two 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 three measures of rectal sensory thresholds. The study found a statistically significantly greater increase in rectal sensitivity with the device turned on in two of the three measures. Among the secondary outcome measures, there was a significantly greater benefit of active treatment on the percentage of successful bowel movements per week and the percentage of episodes with a sense of complete evacuation. In addition to its small sample size, the study was limited by the lack of a wash-out period between treatments, i.e., there could have been a carry-over effect when the device was used first in the on position. Moreover, the authors noted that the patients were highly selected; only 14 of the approximately 1800 patients approached met the eligibility criteria and agreed to participate in the study.

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 one year and had failed medical and behavioral treatments. Constipation was defined as at least one of the following: fewer than two 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 three-week trial period. Criteria included an increase in evacuation frequency to at least three 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 one 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 two 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 two (range, 1 to 9) events per patient were reported; 26 of 58 events (45%) were reported in the first six months after device implantation. The most common reportable events were lack or loss of efficacy (26 of 58 events, 45%), and pain (16 events, 28%). Twenty-eight (48%) of the events were resolved by reprogramming. Surgical interventions were required for 19 (33%) of the events, most commonly permanent electrode replacement (14 events). Three of 38 (8%) patients discontinued use of the device due to reportable events.

Only two small controlled studies are available, both crossover studies; one had only two 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 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 six months) who underwent testing for SNM implantation. After a four-week temporary stimulation phase, 16 of 27 patients (59%) underwent implantation of an InterStim device. In the 16 implanted patients, mean pain on a visual analogue scale was 8.1 before implantation and 2.1 at the six- and 12-month follow-ups. An earlier study by Siegel et al reported on ten patients and stated that nine of the 10 experienced a decrease in pain with SNS stimulation.

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 two types of trial stimulation before permanent implantation of a neuromodulation device. These are percutaneous nerve evaluation (PNE) and Stage 1 (lead implantation) of a two-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 two-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 two trial stimulation techniques. In addition, it would be useful to have data on the optimal approach to using the two-stage surgical procedure. As mentioned previously in the Background section, the two-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 two-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 two-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 three 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 two 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 two 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 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 four to seven of testing). These 15 patients underwent Stage 1 of the two-stage technique. One patient failed the first stage and was explanted. Of the remaining 14 patients, two 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.

Several studies, e.g., Borawski et al and Bannowsky et al, 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 two test procedures. With this type of study (i.e., without follow-up after implantation), it is not possible to conclude whether the two-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.

Practice Guidelines and Position Statements

National Institute for Clinical Evidence

Their 2007 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 two 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.”

American College of Gastroenterology (ACG)

A 2004 practice guideline 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.

American College of Obstetricians and Gynecologists (ACOG)

- A 2005 position statement considered SNS to be beneficial for treating chronic voiding dysfunction.
- 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.

Key Words:

Interstim, incontinence, sacral nerve stimulation, sacral neuromodulation, InterStim® II, InterStim iCon™ Patient Programmer

Approved by Governing Bodies:

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. There has also been research interest in using the device as a treatment of fecal incontinence, constipation, and chronic pelvic pain.

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. All other uses of this device (e.g., fecal incontinence or constipation) would be off-label.

In 2011, the FDA approved the use of InterStim® for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments. The InterStim device has not been specifically approved by FDA for treatment of chronic pelvic pain.

Benefit Application:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.

Current Coding:

CPT codes:

- 64561** Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
- 64581** Incision for implantation of neurostimulator electrodes array; sacral nerve
- 64585** Revision or removal of peripheral neurostimulator electrodes 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 programming
95972	; with intraoperative or subsequent programming; first hour
95973	; each additional 30 minutes after first hour (list separately in addition to code for primary procedure)
A4290	Sacral nerve stimulation test lead, each
E0745	Neuromuscular stimulator, electrical shock unit
E1399	Durable medical equipment, miscellaneous

HCPCS:

L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

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Policy History:

Medical Policy Group, October 2003

Medical Review Committee, December 2003

Medical Policy Administration Committee, December 2003

Medical Policy Group, May 2004 (3)

Medical Policy Administration Committee, May 2004

Available for comment May 17-June 30, 2004

Medical Policy Group, August 2004 (3)

Medical Policy Administration Committee, August 2004

Available for comment August 12-September 25, 2004

Medical Policy Group, August 2006 (3)

Medical Policy Administration Committee, September 2006

Medical Policy Group, August 2009 (1)

Medical Policy Panel, May 2010

Medical Policy Group, June 2010 (3)

Medical Policy Group, November 2010 (3)

Medical Policy Administration Committee, December 2010

Available for comment December 10, 2010 through January 24, 2010

Medical Policy Group, April 2011: (3) Added statement to Approved by Govern. Bodies

Medical Policy Group, December 2011 (3): 2012 Code Updates – verbiage change to 64561, 64581, 64585, 95970, 95972, and 95973.

Medical Policy Group, June 2012 (3): 2012 Updates-Description, Policy, Key Points, & References

Medical Policy Group, December 2012 (3): 2013 Coding Update: Verbiage change to 64561

Medical Policy Panel, April 2013

Medical Policy Group, April 2013 (3): 2013 Updates to Key points and References; minor clarification to policy statement

Medical Policy Group, May 2014 (5): 2014 Coding Update: Deleted code L8680 effective July 1, 2014.

Medical Policy Group, June 2014 (5): 2014 Quarterly Coding Update: Code L8680 did not delete; removed delete date.

Medical Policy Panel, April 2014

Medical Policy Group, July 2014 (4): Added indication of overactive bladder to policy statement. Updated Approved Governing Bodies, Key Points and References.

Medical Policy Administration Committee, August 2014

Available for comment July 28 through September 8, 2014

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.