Subject: Sacral Nerve Stimulation for Incontinence

Overview: Sacral nerve stimulation is used to treat the symptoms of an overactive bladder, including urinary urge incontinence and/or urgency-frequency in patients who have failed or cannot tolerate conventional treatments. It has also been approved by the FDA for treatment of fecal incontinence. It involves applying an electric current to one of the sacral nerves via an electrode placed through the corresponding sacral foramen. The electrode leads are attached to an implantable pulse generator.

Policy and Coverage Criteria:

NOTE: Prior Authorization is NOT required

Sacral Nerve Stimulation is covered for the treatment of non-obstructive urinary retention, urinary urge incontinence, and symptoms of urgency-frequency syndrome in patients who have failed or could not tolerate more conservative treatments. It is also covered for patients with chronic fecal incontinence.

Exclusions: N/A

Supporting Information:

1. Technology Assessment: Sacral nerve stimulation (SNS) uses a small, implanted device to send mild electrical pulses to a nerve located in the lower back. This grouping of nerves, called the sacral nerves, influences the bladder and surrounding muscles that manage urinary function. The electrical stimulation may eliminate or reduce certain bladder control symptoms. It is intended for the treatment of intractable urinary urge incontinence, non-obstructive urinary retention, and urgency/frequency syndrome in adults. For chronic fecal incontinence the device stimulates the sacral nerve which controls the anal sphincter. Patients undergo a two week trial stimulation to determine whether they would benefit from permanent implantation.

2. Literature Review:

Urinary incontinence: A 2012 guideline by the American Urological Association notes, “Clinicians may offer SNS as third-line treatment in a carefully selected patient population characterized by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure.” The guideline also noted SNS has durable treatment effects, but often frequent adverse events. Pettit and Chen (2012) reviewed available evidence around implantable SNS for the treatment of urinary incontinence and found the treatment to be a mainstay for patients who have failed conservative therapy. They point out that SNS is now considered standard of care for urinary voiding disorders. While the mechanism of action remains unclear, the therapy is effective and durable.

A systematic review by Herbison et al. (2009), evaluated eight studies of 500 adults with urge urinary incontinence, overactive bladder syndrome (i.e., urgency or frequency), and urinary retention. Analysis revealed about 50% of patients in the stimulation groups achieved complete continence or an improvement greater than 90% in the main incontinence symptoms, while 87% of patients achieved a 50% improvement. Most of the longer term studies had poor rates of follow up. However, overall they noted that continuous stimulation offers
benefits for carefully selected individuals with overactive bladder syndrome and for those with urinary retention but no structural obstruction. Van Karrebroeck et al. (2007) reported on a prospective, multicenter trial to evaluate the long-term safety and efficacy of SNS in patients with refractory urge incontinence, urgency/frequency, and retention problems. 163 patients were enrolled from 17 centers worldwide. 152 underwent a permanent implantation of the SNS InterStim. After five years of follow up, 68% of patients with urge incontinence, 56% of patients with urgency/frequency, and 71% with retention had successful outcomes. Sutherland et al. (2007) discussed their eleven year experience with SNS for voiding dysfunction in a retrospective review of 104 patients implanted with a pulse generator between 1993 and 2004. The mean follow-up period for patients was 22 months. The authors reported a significant improvement in symptoms for patients with a primary complaint of urinary urgency/frequency. Brazzelli et al. (2006) conducted a systematic review of primary studies evaluating the safety and efficacy of SNS published between 1966 and 2003. Four RCT met the inclusion criteria for patients with urge urinary incontinence. 120 patients were part of this group and showed about 80% achieved continence or greater than 50% improvement in their main incontinence symptoms after SNS. 30 case series studies were evaluated and showed similar results with 67% of patients becoming dry or achieving a greater than 50% improvement in symptoms. The authors noted that while SNS techniques evolved over the years, reported rates of adverse effects have decreased in parallel. Based on their results, the authors concluded SNS is effective for decreasing symptoms in patients with urge incontinence. There are a number of other peer-reviewed reports highlighting the safety and efficacy of SNS as a treatment for urinary incontinence.

Fecal incontinence: A 2013 review of SNS by Noblett and Cadish found there is clinical data to support the long-term efficacy and safety of SNS for the treatment of bladder and bowel dysfunction. Wexner et al. (2010) published results of a prospective multicenter study of sacral nerve stim for fecal incontinence. Patients showing greater than or equal to 50% improvement during test stimulation received permanent implantation of the InterStim device. Primary efficacy objective was to demonstrate that greater than or equal to 50% of subjects would achieve therapeutic success, defined as greater than or equal to 50% reduction of incontinent episodes per week at 12 months compared with baseline. 133 patients underwent test stim with a 90% success rate. 120 (110 female) with a mean age of 60.5 years received permanent implantation. Mean follow-up was 28 months. At 12 months, 83% of subjects achieved therapeutic success and 41% achieved 100% continence. Incontinent episodes decreased from a mean of 9.4 per week at baseline to 1.9 at 12 months and 2.9 at 2 years. No reported unanticipated adverse device effects were associated with the InterStim device. Researchers concluded SNS using InterStim is a safe and effective treatment for patients with fecal incontinence. Madea et al. (2013) published results of SNS for FI at 5 years. Data was collected prospectively from patients who underwent SNS between 2001 and 2006. 101 patients were available for the 5 year evaluation. Results found 42.6% of patients reported favorable outcomes at 5 years. Predictive factors included patient's age, improvement of urge incontinence during percutaneous nerve evaluation, and sustained efficacy during the first 6 months following implantation. A study by Moya et al. (2013) reported results of 50 patients implanted with SNS. The overall mean follow-up period was 55.52 ± 31.84 months. After 6 months, SNS significantly improved FI and positively impacted quality of life, as evidenced by significant improvements in all 4 scales of the FIQLS. Anorectal manometry showed a trend towards an increase in maximum resting pressure and maximum pressure. After the first assessment at 6 months, Wexner score and FIQLS remained stable. Ability to defer defecation was also maintained. During follow-up, 3 patients (6 %) experienced implant site pain and episodes of extremity pain and paresthesias that were refractory to medical management and required device explantation. The implant site infection rate was 2%. The researchers found their results to confirm the safety and efficacy of SNS for treatment of refractory FI. Michelsen et al. (2010) reported six year results of SNS for fecal incontinence. A total 177 patients with fecal incontinence (160 females), median age 59.5 years, underwent a percutaneous nerve evaluation test. Of these patients, 142 had a positive test, including 21 of 25 patients who required a repeat percutaneous nerve evaluation test. Because of a functional failure, 16 patients underwent a revision of the permanent electrode, 7 of whom (44%) were satisfied with the functional result after the revision. Of 126 patients, 15 have undergone an explantation, with an infection rate of only 1.6%. Overall, after a median follow-up of 24 months, the median Wexner incontinence score decreased from 16 (range, 6-20) to 10 (range, 0-20) (P < .0001). In the 10 patients who underwent at least 6 years of treatment, the effect was sustained, as the median Wexner incontinence score decreased from 20 to 7 (P < .0001). The researchers concluded SNS to be a safe and minimally invasive
technique with low morbidity and excellent results which appear to be maintained the first 6 years after the procedure.

An additional study by Matzel et al. (2009) reported results of patients implanted with SNS for treatment of fecal incontinence. Between 1994 to 1999, 12 patients underwent implantation of SNS. 9 patients were eligible for long term analysis, defined as a minimum of 7 years. Functional outcome was monitored prospectively by standardization questionnaire. The recorded frequency of incontinent episodes over 2-week periods and the Wexner Score were obtained yearly after implant. Mean follow up for the 9 patients was 9.8 years. Clinical improvement was significant. Median percentage of incontinent bowel movements/week 40% vs. 0%; median number of incontinent episodes/week, 9 vs. 0; median Cleveland Clinic Score, 17 vs. 10; quality of life improved in all categories. Matzel et al. found SNS for fecal incontinence to be a safe and effective long-term treatment. Clinical outcome is stable over time.

Results of an RCT were reported by Tjandra et al. (2008). The study compared the effect of SNS with optimal medical therapy in patients with severe fecal incontinence. Patients with severe fecal incontinence were randomized to SNS (n=60) or best supportive therapy (n=60), which consisted of pelvic floor exercises, bulking agent, and dietary manipulation. Follow-up was 12 months. With the SNS patients mean incontinent episodes per week decreased from 9.5 to 3.1 and mean incontinent days per week from 3/3 to 1. Perfect continence was accomplished in 25 patients. There was also significant improvement in fecal incontinence quality of life index in all four domains. The control group showed no significant improvement in fecal continence and the fecal incontinence quality of life scores. Tjandra et al. concluded SNS significantly improved the outcome in patients with severe fecal incontinence compared with the control group undergoing optimal medical therapy.

3. Benchmarks:

BCBS MA: 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
  - Non-obstructive urinary retention AND
- There is documented failure or intolerance to at least two conventional therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy) AND
- 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 in I. A (1-3) above are met.
- A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 2 weeks.

Sacral nerve neuromodulation for the treatment of fecal incontinence may be MEDICALLY NECESSARY when ALL of the following criteria are met:

- 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, AND
- Documented failure or intolerance to conventional 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 2 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.

Sacral nerve neuromodulation (SNM) for other urinary/voiding applications, 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 is INVESTIGATIONAL.


Anthem BCBS NH: Placement of a temporary sacral nerve stimulator is considered medically necessary after a positive peripheral nerve evaluation test for urinary urge incontinence and urinary urgency/frequency, when all of the following are met:

• The individual has experienced urge incontinence for a minimum of 12 months duration that is not due to a neurologic condition and has resulted in significant disability (frequency or severity impacts ability to work or participate in activities outside of the home); and
• The individual is refractory or could not tolerate a minimum of 12 consecutive months of conservative treatments (exercises, medication); and
• The individual is an appropriate surgical candidate for permanent implantation.

Placement of a temporary sacral nerve stimulator is considered medically necessary after a positive peripheral nerve evaluation test for non-obstructive urinary retention when the following are met:

• The individual is an appropriate surgical candidate for permanent implantation;
• The individual has experienced urinary retention for a minimum of 12 months duration that is not due to a neurologic condition and has resulted in significant disability (frequency or severity impacts ability to work or participate in activities outside of the home); and
• One of the following additional criteria is met:
  o The individual is refractory or could not tolerate a minimum of 12 consecutive months of pharmacotherapy; or
  o Intermittent catheterizations have failed or are not well tolerated after a trial of 12 consecutive months.

A permanent sacral nerve stimulator is considered medically necessary for those with refractory urge incontinence, urge/frequency incontinence or non-obstructive urinary retention who have had a successful trial of the temporary sacral nerve stimulator and are an appropriate surgical candidate for permanent implantation.

Successful trial is defined as:

• Urinary retention: At least a 50% reduction in catheter volume/catheterization;
• Urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes or the number of pads/diapers used per day;
• Urinary urge/frequency: At least 50% reduction in one of the following: number of voids daily, volume per void and frequency per void.

Placement of a temporary sacral nerve stimulator is considered medically necessary for the treatment of fecal incontinence when all of the following criteria are met:

• Incontinent episodes averaging greater than or equal to 2 per week for 6 consecutive months or for 12 consecutive months after vaginal childbirth; and
• The medical record shows failure of or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); and
• The individual is an appropriate surgical candidate.

A permanent sacral nerve stimulator is considered medically necessary for the treatment of fecal incontinence when the individual had a successful trial of the temporary sacral nerve stimulator and is an appropriate surgical candidate for permanent implantation. Successful trial is defined as:

• The individual has met the criteria above for evaluation for a temporary sacral nerve stimulator; and
• Temporary sacral nerve stimulation shows at least a 50% improvement in symptoms.

http://www.anthem.com/medicalpolicies/policies/mp_pw_c140988.htm

Aetna: Aetna considers sacral nerve stimulation (sacral neuromodulation) medically necessary for the treatment of members with chronic fecal incontinence, who have had an inadequate response to conservative treatments
(e.g., biofeedback, dietary management, pharmacotherapy, strengthening exercises), and who have a weak but structurally intact anal sphincter. Initially, a temporary percutaneous peripheral nerve electrode is considered medically necessary for testing over a 2- to 3-week period. Implantation of a permanent implantable pulse generator is considered medically necessary for members who have significant benefit from the temporary percutaneous peripheral nerve stimulation.

http://www.aetna.com/cpb/medical/data/600_699/0611.html

4. Governmental/Professional Organizations:

FDA: The InterStim® System for Urinary Control (Medtronic, Inc., Minneapolis, MN) is approved by the FDA for the treatment of nonobstructive urinary retention, urinary urge incontinence, and symptoms of urgency-frequency syndrome in patients who have failed or could not tolerate more conservative treatments.

The InterStim device received FDA approval March 14, 2011 for the treatment of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/RecentlyApprovedDevices/ucm249208.htm

CMS: Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. Sacral nerve stimulation 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:

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


Codes:

CPT Codes:
64561: Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64581: Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64585: Revision or removal of peripheral neurostimulator electrodes
64590: Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling
64595: Revision or removal of peripheral pulse generator or receiver

HCPCS Codes:
A4290: Sacral nerve stimulation test lead, each
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: External recharging system for implanted neurostimulator, replacement only
L8689: Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
References: