



# Cigna Medical Coverage Policy

**Subject** Sacral Nerve Stimulation For  
Urinary Voiding Dysfunction  
and Fecal Incontinence

**Effective Date** ..... 9/15/2014  
**Next Review Date** ..... 9/15/2015  
**Coverage Policy Number** ..... 0404

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## Coverage Policy

### Urinary Voiding Dysfunction

Cigna covers a percutaneous screening trial of sacral nerve stimulation (SNS) as medically necessary for an individual with urinary voiding dysfunction and failure of, contraindication to, or intolerance to conservative medical management for ANY of the following indications:

- urinary urge incontinence
- nonobstructive urinary retention
- urinary urgency/frequency syndrome

Cigna covers permanent SNS implantation as medically necessary when BOTH of the following criteria are met:

- the individual has met the criteria for a percutaneous screening trial of SNS
- the individual experienced a beneficial clinical response to a percutaneous screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms

### Fecal Incontinence

Cigna covers a percutaneous screening trial of SNS for fecal incontinence as medically necessary when ALL of the following criteria are met:

- failure of, contraindication to, or intolerance to conservative medical management
- sphincter surgery is either not indicated or is contraindicated.
- absence of a significant anorectal malformation or chronic inflammatory bowel disease involving the anus
- fecal incontinence is not secondary to another neurological condition such as peripheral neuropathy or complete spinal cord injury

**Cigna covers permanent SNS implantation for fecal incontinence as medically necessary when BOTH of the following criteria are met:**

- the individual has met the criteria for a percutaneous screening trial of SNS
- the individual experienced a beneficial clinical response to a percutaneous screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms

**Cigna does not cover SNS for the treatment of any other indication because it is experimental, investigational or unproven.**

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## General Background

Sacral nerve stimulation (SNS), also known as sacral nerve neuromodulation, involves the implantation of a permanent device that modulates the neural pathways. The exact mechanism of action is unclear (Mellgren, 2010, Herbison, 2009). Sacral nerve stimulation (SNS) applies a low amplitude electrical current to a sacral nerve through an electrode that is placed through a corresponding sacral foramen. The stimulation of the sacral nerves leads to recruitment of the pelvic floor musculature and pelvic organs, leading to improvement in pelvic floor function. The third sacral foramen is the level at which an optimal response is most commonly elicited. The third sacral nerve root contains afferent sensory and efferent autonomic motor nerves and voluntary somatic fibers, which may, alone or in harmony, create the beneficial effect elicited by SNS (Mellgren, 2010).

Prior to the implantation of a permanent SNS system, patients are screened for potential therapeutic benefit by undergoing a trial in which a temporary electrode is percutaneously introduced into the left or right sacral nerve foramen and an external device provides continuous stimulation. The length of the screening trial varies. The patient must demonstrate a positive therapeutic response to qualify as a candidate for permanent implantation (Peeren, 2005).

When the screening trial demonstrates successful results, permanent SNS system placement can be performed by means of an implantable pulse generator (IPG) which is positioned surgically in the upper buttock region. The IPG is connected to an electrical lead in contact with one side of the appropriate sacral nerve root, most often the third sacral (S3) vertebra. Implantation is considered to be a minimally invasive procedure and is performed under general anesthesia. Complications to SNS include device-related pain, need for revision, infection, and neurologic complications.

SNS has been proposed for the treatment of urinary voiding dysfunction, including intractable urinary urge incontinence, nonobstructive urinary retention, urinary urgency/frequency syndrome in adults, fecal incontinence, and several other indications.

### Urinary Voiding Dysfunction

Urinary voiding dysfunction is usually defined as the inability to control urination. Urinary voiding disorders are generally divided into five types, depending on the pathophysiology involved: urge incontinence—a subtype is urgency-frequency syndrome, overflow incontinence, also known as urinary retention, stress incontinence, mixed incontinence, functional incontinence.

Treatment options for urinary voiding disorders may include behavioral strategies, pharmacological interventions, temporary electrical stimulation, or reconstructive surgery. Less invasive modalities are generally used initially before irreversible, reconstructive surgery is considered.

SNS may be indicated in patients who demonstrate at least 50% urinary incontinence symptom relief during percutaneous test stimulation and who have failed or not tolerated more conservative treatments (e.g., behavioral strategies, pharmacological interventions). The criteria for a positive response vary slightly; however, at least a 50% improvement in one or more primary symptoms is considered the standard for a clinically significant response (Schmidt, 1999). It is not proposed for the treatment of stress incontinence, the most common type of urinary dysfunction (Hassouna, 2000).

The precise mode of action of neuromodulation on the lower urinary tract is unclear. When a nerve is stimulated, signals travel both toward the periphery and toward the central nervous system (Herbison, 2009). According to the manufacturer of the InterStim® System for Urinary Control (Medtronic, Inc., Minneapolis, MN), SNS is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture. Medtronic also states that the safety and effectiveness of SNS has not been established for bilateral stimulation, patients with neurological disease origins (e.g., multiple sclerosis), pregnancy and delivery or for children under the age of 16 (Medtronic, Inc., 2012).

Sacral nerve stimulation is considered an appropriate treatment option for individuals with refractory voiding dysfunction, with failure of, or contradiction or intolerance to conservative medical management after a 50% improvement is noted in response to a percutaneous screening trial.

**U.S. Food and Drug Administration (FDA):** The InterStim® System for Urinary Control (Medtronic, Inc., Minneapolis, MN) received premarket approval from the FDA “for the treatment of urinary urge incontinence, urinary retention, and significant symptoms of urgency/frequency in patients who have failed or could not tolerate more conservative treatments.” In August 2001, the FDA approved the Model 3550-03 Twist-Lock Screening Cable and Model 3550-05 Percutaneous Extension and Tunneling Tool Kit for temporary SNS as part of a staged implant screening technique for patients who had inconclusive results following standard percutaneous testing (FDA, 2002). In 2007 the Urgent® PC Neuromodulation System (Uroplasty, Inc., Minnetonka, MN) received 510K approval as a substantially equivalent device. The Urgent PC Neuromodulation System is intended to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence.

**Literature Review:** Several randomized clinical trials (RCTs), prospective case series, retrospective analyses and systematic reviews have demonstrated >50% improvement in incontinence symptoms, decrease in the number of daily catheterizations required, an increase in the volume of urine obtained per void, and a decrease in post-void residual urine volume with the use of sacral nerve stimulation (SNS) (Herbison, 2009; White, 2008; van Kerrebroeck, 2007; Sutherland, 2007; Brazzelli, 2006; Everaert, 2004; Chartier-Kastler, 2004). Adverse events reported include changes in stimulation sensation, loss of efficacy, pain at the implantation site, and the need for intravenous antibiotics.

White et al. (2008) retrospectively examined long-term efficacy and durability of SNS for refractory urinary retention in 40 patients who had previously undergone SNS. At a mean follow-up of 40.03 months, 85.7% of patients demonstrated sustained improvement in symptoms. Among those with complete retention, significant improvement occurred in the number of catheterizations/day and the volume/catheterization ( $p < 0.001$ ). Among those with incomplete retention, significant improvement occurred in the postvoid residual urine volume ( $p < 0.001$ ).

Van Kerrebroeck et al. (2007) reported long-term results of a five-year prospective multi-center study evaluating the safety and efficacy of SNS in patients with refractory urge incontinence, urgency frequency, and retention. One hundred sixty-three patients enrolled in the study and after undergoing test stimulation 152 underwent SNS implantation. Implanted devices varied between patients. Three-day voiding diaries were collected annually for five years-diary variables differed according to the type of urinary disorder. Simple uroflow and quality of life questionnaires, such as the Short Form-36 and the Beck Depression Inventory were used. Detailed data were also collected on any concomitant treatment for the urological condition and on any therapy or patient related complications. Clinical success was defined as  $\geq 50\%$  improvement in baseline. For patients with urge incontinence mean leaking episodes per day decreased from 9.6 to 3.9 at five years. For patients with urgency frequency, mean voids per day decreased from 19.3 to 14.8 and mean volume voided per void increased from 92.3 ml to 165.2 ml. For patients with retention the mean volume per catheterization decreased from 379.9 ml to 109.2 ml, and the mean number of catheterizations decreased from 5.3 to 1.9. All changes were statistically significant ( $p < 0.001$ ). No life threatening or irreversible adverse events occurred; however, in 102 patients 279

device or therapy related adverse events were observed. At five years after implantation, 68% of patients with urge incontinence, 56% with urgency frequency and 71% with retention had successful outcomes.

**Systematic Reviews:** In a systematic review by Herbison et al. (2009), involving twelve reports of eight randomized studies of 500 adults with urge urinary incontinence, overactive bladder syndrome (i.e., urgency or frequency), and urinary retention, about 50% of patients in the stimulation group achieved complete continence or an improvement greater than 90% of the main incontinence symptoms. Eighty-seven percent of patients achieved a 50% improvement. In all reports, participants had failed conventional treatments before randomization. It is unclear whether the studies all used the same implant. The authors noted that several long-term studies had poor rates of follow-up. Thirty percent or more potentially eligible patients were not implanted and 30% or more of those implanted did not gain benefit. Overall continuous stimulation offers benefits for carefully selected individuals with overactive bladder syndrome and for those with urinary retention but no structural obstruction.

The Agency for Healthcare Research and Quality (AHRQ, 2007) reported results of a systematic review of several small RCTs, three large RCTs and one prospective cohort of adults in a community setting to determine the benefit of sacral nerve root neuromodulation for urinary incontinence. The review suggested that implantation of a multiprogrammable neurostimulator cured 47% of participants with urge urinary incontinence compared to standard medical therapy. Sacral root neuromodulation resulted in urge continence more than nine times more often than conservative management with medications or pelvic floor muscle training. Evidence from these studies suggested that sacral nerve root neuromodulation can improve predominantly urge incontinence in adults but that curative results are not consistent.

Brazzelli et al. (2006) performed a systematic review on the efficacy and safety of SNS in patients with urge urinary incontinence in four RCTs and 30 case series. Results from the randomized trials (n=120) showed that 80% of participants achieved continence or >50% improvement in their main incontinence symptoms after SNS compared with 3% of the controls who received conservative treatments. The case series studies showed similar results, with 67% of patients becoming dry or achieving a >50% improvement in symptoms. There were adverse events documented in 27 studies, most commonly involving pain, migration of lead, and replacement or repositioning of the IPG.

There is sufficient high quality controlled clinical trial data to demonstrate the safety and effectiveness of sacral nerve stimulation for the treatment of individuals with refractory voiding dysfunction, with failure of, or contradiction or intolerance to conservative medical management after a 50% improvement is noted in response to a percutaneous screening trial.

**Professional Societies/Organizations:** The American Urologic Association (AUA)/ Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guidelines on the management of non-neurogenic OAB state that sacral neuromodulation may be offered as a third line treatment in a carefully selected patient population such as those with severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure (Gormley, et al., 2012).

Recommendations by the AUA (2000) note: "There is sufficient evidence both from randomized, controlled trials as well as from objectively performed nonrandomized, control data, which would support the utilization of sacral nerve stimulation as an intervention for refractory motor urgency incontinence as well as urinary urgency, frequency, and urinary retention in the treatment of voiding dysfunction of the lower urinary tract." The AUA recommends SNS as a standard therapy for patients with refractory voiding dysfunction (motor urge incontinence, urinary urgency and frequency, and urinary retention) in those patients who have failed behavioral therapies (fluid restriction, dietary modification, voiding re-training, and/or specific pelvic floor physiotherapy) and anticholinergic agents, either due to an inability to tolerate those agents, or due to persistent symptoms despite those agents.

**Use Outside of the US:** The consensus guideline from the European Association of Urology (EAU) (2010) notes "Sacral neuromodulation appears to have benefit for patients with urgency incontinence, as well as urgency and frequency."

Regarding SNS for urinary voiding dysfunction, the National Institute for Clinical Excellence (NICE) notes that current evidence on the safety and efficacy of sacral nerve stimulation for urge incontinence and urgency-

frequency appears adequate to support the use of this procedure. The diagnosis should be defined as clearly as possible and the procedure limited to patients who have not responded to conservative treatments such as lifestyle modifications, behavioral techniques and drug therapy. Patients should be selected on the basis of their response to peripheral nerve evaluation (2006).

### **Fecal Incontinence**

Fecal incontinence is the inability to control bowel movements leading to feces leaking from the rectum (American Academy of Family Physicians [AAFP], 2011). The reported prevalence in the general population is 2% to 3%. Severe fecal incontinence can be socially isolating as an individual with the condition may alter his/her lifestyle to accommodate the likelihood of bowel leakage.

According to the AAFP, fecal incontinence may be caused by several factors including muscle damage, such as that experienced after childbirth, or after rectal surgery, or from damage to the nerves that control the anal muscle or regulate rectal sensation. Additionally, it may be caused by a reduction in the elasticity of the rectum, which shortens the time between the sensation of the stool and the urgent need to have a bowel movement. Surgery or radiation injury can scar and stiffen the rectum. Inflammatory bowel disease can also make the rectum less elastic (AAFP, 2011).

Treatment depends on the cause of the incontinence and may include dietary changes, drug therapy, bowel training, or surgery (AAFP, 2011). Fecal incontinence remains a therapeutic problem in many patients when conservative measures, such as dietary advice, pelvic floor exercises and medical therapy with bulking agents, fails and sphincter repair is unsuccessful or inappropriate (Chan, 2008; Leroi, 2005; Jarrett, 2004). Sacral nerve stimulation (SNS) has been proposed for the treatment of fecal incontinence.

The exact mechanism of action of SNS for fecal incontinence remains unclear. According to Gladman (2008), "Although it was initially thought that SNS would directly augment anal sphincter function and improve fecal incontinence, the observation that improved continence occurs without change in anal sphincter function has led to the suggestion that SNS has predominantly suprasphincteric effects. The mechanism of action of SNS is not conclusively proved and may involve direct effects peripherally on colorectal sensory or motor function, or central effects at the level of spinal cord or brain." Further neurophysiological research is necessary to understand the mechanisms of SNS (Mellenhorst, 2007).

Indications and patient selection for the use of sacral nerve stimulation (SNS) for the treatment of fecal incontinence continue to evolve. Initial study eligibility included patients with a functionally deficient but morphologically intact anal sphincter. More recently, inclusion criteria has been extended to include those with external and internal sphincter defects, secondary to cauda equina syndrome, scleroderma, rectal prolapse repair, low anterior resection of the rectum, and partial spinal injuries (Gladman, 2008; Jarrett, 2004).

**U.S. Food and Drug Administration (FDA):** In March 2011, Medtronic, Inc. (Minneapolis, MN) received premarket approval from the FDA for the Medtronic® InterStim® Therapy System. This device is indicated for the treatment of chronic fecal incontinence in patients who have failed or are unable to tolerate more conservative treatments (FDA, 2011). Medtronic is required to continue follow-up of the patients enrolled in the premarket InterStim trial for five years. The primary objective of the study, titled, "InterStim Sacral Nerve Stimulation Therapy for Bowel Control: Fecal Incontinence Post Approval Study (FI-PAS)" is to continue evaluation of incontinent episodes through five years post implantation of the device, including tracking of adverse events.

**Literature Review:** Randomized controlled data are limited regarding the effects of SNS; however, there is sufficient evidence to support the use of SNS for the treatment of fecal incontinence following a successful percutaneous trial. A number of prospective case series and retrospective reviews have noted improvements in the frequency of incontinence episodes and quality of life measures as self-reported in bowel diaries and quality of life scales (Hull, et al., 2013; Damon, et al., 2013; Devroede, 2012; Boyle, 2011; Mellgren, 2011; Uludag, 2011; Michelson, 2010; Wexner, 2010; Matzel, 2009; Chan, 2008; Meurette, 2008; Mellenhorst, 2006; Matzel, 2004).

Tjandra et al. (2008) published outcomes of the largest randomized controlled trial (RCT) to date involving 120 patients; 60 were randomized to the SNS group and 60 patients were randomized to best supportive therapy (i.e., pelvic floor exercises, bulking agents, dietary modifications, biofeedback). Fifty-four patients in the SNS

group had  $\geq 50\%$  improvement in continence during the screening period with 53 patients undergoing SNS implantation. Follow-up was 12 months. Both groups were assessed at baseline, three, six, and 12 months.

The control group demonstrated no significant improvements in fecal continence as assessed by bowel diary, the Wexner score, and several quality of life scales. In the SNS group, mean incontinent episodes per week significantly improved at six and 12 months, as did mean incontinent days per week ( $p < 0.0001$  and  $0.0001$ , respectively). Urge and passive incontinence also improved. Ability to defer defecation improved significantly but the ability to completely empty the bowel was not affected. One hundred percent fecal competence was achieved in 47.2% of patients. According to the authors, improvement in quality of life was noted immediately after implantation of the SNS, with significant improvement in all domains ( $p < 0.0001$ ). None of the patients had worsening of fecal incontinence as a result of SNS. There were no statistically significant changes in the maximum resting and squeeze anal canal pressures in either group. Adverse events in the SNS group included seroma (2%), pain at the implant site (6%) and tingling in the vaginal area (9%). In the control group six patients complained of constipation due to Immodium use. The authors note that the presence of a control group helps reject the concept of a placebo effect. Data suggest that SNS may result in a decrease in the number incontinent episodes per week.

Leroi et al. (2005) reported outcomes from a randomized double-blind crossover study involving 34 patients with fecal incontinence. Patients initially underwent peripheral nerve evaluation testing and if  $\geq 50\%$  improvement in incontinence was demonstrated they progressed to sacral nerve stimulation (SNS) implantation. All thirty-four patients received SNS; 27 patients were randomized to the crossover period, and 24 completed the study.

Outcome measures were frequency of fecal incontinence and urgency episodes, delay in postponing defecation, score severity, feeling of improvement, preference for ON or OFF mode of stimulation, quality of life, and manometric measurements. Follow-up was 12 months. There was a significant treatment effect with a decrease in the median frequency of FI episodes between the ON and OFF periods; however, median incontinence episodes decreased in both the ON and OFF periods (90% versus 76%, respectively), as did defecation postponement (89% versus 63%, respectively). There was no significant change in the frequency of urgency episodes, the delay in postponing defecation, or the number of bowel movements per week between the periods of stimulation. There was improvement in the Cleveland Clinic incontinence score from baseline but no statistically significant difference between scores in the ON compared to the OFF periods. Additionally, there was no correlation between changes in the frequency of urgency episodes, delay in postponing defecation, Cleveland Clinic score, and changes in anal resting pressure, maximal squeeze pressure, squeeze pressure duration, threshold, constant sensation, and maximum tolerated volumes between the baseline and final periods. No significant change in the maximum anal resting pressure, squeeze pressure increment, and duration of voluntary contraction was noted between the two stimulation periods. Data suggest a treatment effect in regards to the frequency of episodes with the use of SNS. Additionally, improvement was noted in incontinence scores from baseline compared to periods of stimulation results.

In a prospective uncontrolled trial investigating the effectiveness of SNS for fecal incontinence, Wexner et al. (2010) evaluated 285 patients. One hundred thirty-three patients underwent peripheral nerve stimulation and 120 of those individuals received permanent SNS. Mean follow-up was 28 months. Study participants were requested to complete a five-question bowel diary at baseline, during test stimulation, and at three, six, and 12 months and annually after study closure. Quality of life and well-being were also assessed by additional questionnaires. At 12 months, 83% achieved therapeutic success defined as achieving  $\geq 50\%$  reduction in the number of incontinent episodes per week compared to the baseline; 85% achieved therapeutic success at 24 months. Forty percent of those receiving SNS achieved 100% improvement in incontinent episodes per week and incontinent days per week at 12 months. Incontinence episodes decreased from a mean of 9.4 per week at baseline to 1.9 at 12 months, and 2.9 at two years. Adverse event (AE) rates were high with 696 AEs reported. Three hundred seven AEs in 96 patients were related to the device or therapy. Twenty-six AEs were considered serious and included implant site pain, hematomas, lead fractures, lead migrations or dislodgments, extremity pain, skin irritation, paresthesias, implant site infection, change in sensation of stimulation, urinary incontinence, and diarrhea. 10.8% of patients experienced implant site infection and 5.8% required surgical removal of the implant. Study limitations include an uncontrolled, nonrandomized design and short-term follow-up.

Mellgren et al. (2011) reported results of a three-year follow-up assessment of the trial by Wexner et al. Of 120 patients receiving chronic SNS, eighty-three patients completed part or all of the assessment, with 86% of patients reporting  $\geq 50\%$  reduction in the number of incontinent episodes per week compared with baseline.

Perfect continence was reported by 40% of study participants. Improvements in the Fecal Incontinence Quality of Life scale were reported at 12, 24, and 36 months of follow-up. Device- or therapy-related adverse events included implant site pain (28%), paresthesia (15%), change in the sensation of stimulation (12%), and infection (10%). Limitations include an uncontrolled, nonrandomized study design.

**Meta-Analysis and Systematic Reviews:** Tan et al. (2011) performed a meta-analysis of thirty-four studies, including 944 patients undergoing peripheral nerve evaluation; 665 underwent permanent sacral nerve stimulation (SNS). Study design included twenty-eight prospective non-randomized trials; two retrospective trials, one prospective cross-sectional study, two double-blind cross-over trials, and a randomized controlled trial. Follow-up ranged from two weeks to 35 weeks. All studies reported on at least one outcome of interest. Studies were analyzed for functional outcomes (i.e., weekly incontinence episodes, Wexner (Cleveland) incontinence scores, and ability to defer defecation.), Quality of Life outcomes (i.e., SF-36 questionnaire), fecal incontinence quality of life (FIQL) questionnaire (the American Society of Colon and Rectal Surgery [ASCRS] quality of life questionnaire), anal manometry (i.e., resting and squeeze pressures), and rectal sensitivity (i.e., threshold, urge and maximum tolerable volumes). Regarding functional outcomes, twenty-eight studies reported on incontinence episodes per week; all studies reported a decrease following SNS, compared with conservative therapy ( $p < 0.001$ ). Sixteen studies reported at the time patients were able to defer defecation; seven of these were excluded from analysis as data were reported in groups. In the nine studies included in the analysis there was a significant increase in the ability to defer defecation following sacral nerve stimulation ([SNS],  $p < 0.001$ ). Regarding Quality of Life outcomes, there was an increase in the weighted mean difference of all SF-36 outcomes in favor of sacral nerve stimulation (SNS), with all but one (bodily pain,  $p = 0.13$ ) reaching significance. Overall, there was a significant increase in the SNS group in all subcategories of the FIQL questionnaire. In the studies included in the analysis for resting and squeeze pressure, both pressures were found to be significantly higher in the SNS group ( $< 0.001$ ). Regarding rectal sensitivity, twenty-two studies reported on threshold, 21 on urge and 20 on maximum tolerable volumes. Outcomes were significant only for threshold volume ( $p = 0.03$ ). Decreases in urge volume and maximum tolerable volume did not reach statistical significance ( $p = 0.25$  and  $p = 0.48$ , respectively). The most common complications among the 665 patients that underwent permanent SNS implantation were pain or local discomfort (6%), lead displacement or breakage (4%), infection (3%) and sarcoma (3%). The authors note that “the wide range of patients and consistently positive results in functional outcomes suggest that a placebo effect is unlikely; but further randomized controlled trials would be useful in confirming this.” The authors also note that SNS improves functional outcomes and quality of life in patients with fecal incontinence where conventional non-surgical therapies have failed.

Moat et al. (2008) performed a systematic review of three randomized studies involving a total of 38 patients. One study included 34 patients; each of the other studies included two patients. Thirty-one patients received sacral nerve stimulation (SNS). Two studies assessed the effects of SNS for fecal incontinence ( $n = 36$ ); one assessed the effects of SNS on constipation ( $n = 2$ ). All three studies had a double-blinded crossover design. According to the authors the very limited evidence suggests that for some selected patients, SNS can reduce episodes of fecal incontinence and urgency, and improve the ability to defer defecation, leading to a better quality of life. However, a minority may get worse despite apparently successful testing before permanent implantation.

The Agency for Healthcare Research and Quality (AHRQ, 2007) reported results of a systematic review of several studies examining the effects of electrical stimulation or neuromodulation (i.e., SNS) on fecal incontinence. AHRQ noted that individualized sacral nerve continuous stimulation improved incontinence in 89 % of patients with severe baseline incontinence compared to 17 percent after sham stimulation. However, the treatments did not improve quality of life with random differences after active and sham stimulation. All randomized controlled trials (RCTs) reported small inconsistent differences in anal manometry outcomes after active stimulation compared to the control. According to AHRQ electrical stimulation did not improve fecal incontinence in the majority of RCTs. “The significant relative improvement after sacral nerve stimulation in patients with severe baseline incontinence requires future confirmation in a large well designed RCT with long-term follow-up.”

Regarding the use of self-report questionnaires to assess fecal incontinence, AHRQ also noted “Few validated questionnaires and instrumental methods were examined to detect the presence and baseline of causes for fecal incontinence with no consensus on which test is the gold standard. Patient reports do not correlate well with anatomical and physiological measures and anal manometry does not correlate well with ultrasonography or sigmoidoscopy. The severity and impact of incontinence on quality of life can be estimated from self-reported

frequency, amount of leakage, and restrictions on daily activities, but not from instrumental methods. However, treatment decisions are made based on objective measures of incontinence. Instrumental physiological measurements that are associated with patient outcomes and may reflect better effects of different interventions should be analyzed in well-designed experiments.”

In a systematic review Jarrett et al. (2004) analyzed the safety and effectiveness of SNS for the treatment of fecal incontinence. Six patient series and one double-blind crossover study involving 266 patients who had failed maximum conservative therapy and had undergone peripheral nerve testing as a screen for SNS eligibility were assessed. Fifty-six percent of the patients underwent permanent SNS. Complete continence was reported in 41% to 75% of patients, and there was  $\geq 50\%$  improvement in the number of incontinence episodes in 75% to 100% of patients after permanent implantation. The assessment noted that overall, anal resting pressure does not appear to be significantly changed in patients with permanent SNS, but an increase in maximal squeeze pressure has been shown in some studies. Patients undergoing permanent implantation reported having 19 adverse events, including lead migration, pain, and infection. The authors note several study limitations including that most of the data reviewed came from patient series, rather than controlled studies, and follow-up is generally short-term. According to the authors, data was probably prospective but it was unclear from the reports. Additionally, no study compared SNS directly with another treatment for fecal incontinence or constipation. Nonetheless, the authors noted that evidence from the included studies suggest that permanent SNS substantially improves continence in patients with severe fecal incontinence resistant to medical treatment.

Although randomized controlled trial data are limited prospective and retrospective data suggest that sacral nerve stimulation (SNS) may improve the number of incontinence episodes and quality of life measures as reported by study participants. It is noted the number of adverse events reported in some studies is not insignificant with infection rates of 6-10.8%, and stimulator removal rates of 12%. However, SNS is considered an acceptable treatment for selected individuals with fecal incontinence.

**Professional Societies/Organizations:** On behalf of the American College of Gastroenterology ([ACG], 2004), Satish et al. published consensus guidelines regarding the diagnosis and management of fecal incontinence. Satish notes, “An alternative treatment may be sacral nerve stimulation. However, the precise indication for SNS, its comorbidity, its long-term outcome, its efficacy, remains to be defined.”

Guidelines issued by the American Society of Colon and Rectal Surgeons (2007) state that SNS is a promising modality for fecal incontinence (Tjandra, et al., 2007).

**Use Outside of the US:** On behalf of the International Consultation on Urologic Disease, Abrams et al. (2010) published the Fourth International Consultation on Incontinence, Recommendations of the International Scientific Committee: Evaluation and Treatment of Urinary Incontinence, Pelvic Organ Prolapse, and Fecal Incontinence. Regarding fecal incontinence the Consultation notes “The surgical approach to the incontinent patient is dictated by the presence and magnitude of an anatomic sphincter defect. If no defect is present, the patient should undergo percutaneous nerve evaluation (PNE), which, if successful, should lead to SNS.”

The Recommendations further note “For patients with sphincter defects of less than 180 degrees, sphincteroplasty has been conventional therapy. However, as long-term outcome of sphincteroplasty appears to deteriorate with time, and SNS has been proven effective in many patients with sphincter defects, there is a trend towards initial evaluation by PNE followed by, if successful, SNS. Patients with sphincter defects of greater than 180 degrees or major perineal tissue loss require individualized treatment. In some cases, initial reconstruction can be performed. Should incontinence persist, alternatives include stimulated muscle transposition, artificial anal sphincter implantation, or SNS. For patients who remain incontinent following sphincteroplasty, repeat endoanal ultrasound should be undertaken to reassess the status of the repair. If there is a persisting sphincter defect, repeat sphincteroplasty can be considered. Alternatively, such patients can undergo individualized therapy, including sacral nerve stimulation.” “For patients who remain incontinent despite a satisfactory sphincteroplasty, sacral nerve stimulation is recommended. Patients who have failed sacral nerve stimulation can be considered for sphincteroplasty if a sphincter defect is present.”

Regarding the use of sacral nerve stimulation (SNS) for the treatment of fecal incontinence, the National Institute for Clinical Excellence (NICE) (2007) notes, “A trial of temporary SNS should be considered for people with fecal incontinence in which sphincter surgery is deemed inappropriate. These may be patients with intact anal sphincters, or those with sphincter disruption. In those with a defect, contraindications to direct repair may



include atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter, or a poor-quality muscle.” “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 fecal incontinence should be offered SNS on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success.”

### Other Indications

Less commonly SNS has been proposed for the treatment of various other conditions such as constipation and pelvic pain; however, data are limited and there is insufficient evidence in the peer-reviewed scientific literature to support safety and effectiveness. At present, the role of SNS for indications other than urinary urge incontinence, nonobstructive urinary retention, urinary urgency/frequency syndrome, and fecal incontinence has not been established.

### Summary

Several systematic reviews, randomized clinical trials and prospective studies have demonstrated a decrease in the number of daily catheterizations required, an increase in the volume of urine obtained per void, and a decrease in postvoid residual urine volume in individuals with urinary voiding dysfunction (i.e., urinary urge incontinence, nonobstructive urinary retention, and urinary urgency/frequency syndrome) treated with sacral nerve stimulation (SNS) after demonstrating at least a 50% improvement in incontinence symptoms in response to a percutaneous screening trial of SNS.

The growing body of evidence evaluating SNS for fecal incontinence suggests that treatment with SNS results in decreased episodes of incontinence and improved quality of life in a subset of individuals. This group includes those in whom a primary neurological condition has been ruled out, sphincter surgery is either not indicated or is contraindicated, there is an absence of a significant anorectal malformation or chronic inflammatory bowel disease involving the anus, and at least 50% improvement in incontinence symptoms has been achieved in response to a percutaneous screening trial of SNS.

Clinical utility has not been established, and SNS is not yet considered a standard treatment option for any other condition.

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## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

### Covered when medically necessary:

CPT <sup>®</sup> * Codes	Description
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

HCPCS Codes	Description
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1897	Lead, neurostimulator, test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each

L8682	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

**\*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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