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Medical Policy Manual

Topic: Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Sacral nerve neuromodulation (SNM), previously known as sacral nerve stimulation is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. 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.

Treatment using sacral nerve neuromodulation (SNM) is one of several alternative modalities for patients with fecal or urinary incontinence who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

- *Urge incontinence* is defined as leakage of urine when there is a strong urge to void.
- *Urgency-frequency* is an uncontrollable urge to urinate, resulting in very frequent, small volumes and is a prominent symptom of interstitial cystitis (also called bladder pain syndrome).
- *Urinary retention* is the inability to completely empty the bladder of urine.
- *Fecal incontinence* can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and

involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

Prior to implantation of the permanent device, patients undergo a peripheral nerve stimulation test to estimate potential response to SNM. This procedure is done 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 permanent device is implanted with the patient under general anesthesia. An incision is made over the lower back and the electrical leads are placed in contact with the sacral nerve root(s). The wire leads are extended through a second incision underneath the skin across the flank to the lower abdomen. Finally, a third incision is made in the lower abdomen where the pulse generator is inserted and connected to the wire leads. Following implantation, the physician programs the pulse generator to the optimal settings for that patient. The patient can switch the pulse generator between on and off by placing the control magnet over the area of the pulse generator for 1-2 seconds.

Regulatory Status

In 1997, the Medtronic Interstim® Sacral Nerve Stimulation (SNS)™ system received U.S. Food and Drug Administration (FDA) approval for marketing for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. In 1999 the device received FDA approval for the additional indications of urgency-frequency and urinary retention in patients without mechanical obstruction.

In 2006, the Medtronic Interstim® II System received FDA approval for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original system and is reported to be suited for those with lower energy requirements or small stature. The device also includes updated software and programming options.

In 2011, the Medtronic InterStim System received FDA approval for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.

Note: Sacral nerve neuromodulation should be distinguished from pelvic floor stimulation. Pelvic floor stimulation refers to electrical stimulation of the pudendal nerve. This therapy is addressed separately in Medical Policy, Allied Health, No. 4.

MEDICAL POLICY CRITERIA

I. Urinary Incontinence and Non-obstructive Retention

A. A *trial period* of sacral nerve neuromodulation (peripheral nerve stimulation test) with a

temporarily implanted lead may be considered **medically necessary** in patients who meet **all** of the following criteria (I.A.1-3):

1. There is a diagnosis of at least one of the following:
    a. Urge incontinence
    b. Urgency-frequency syndrome
    c. Non-obstructive urinary retention
2. There is documented failure or intolerance to at least two conventional conservative therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy)
3. Incontinence is not related to a neurologic condition;

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

1. All of the criteria in I. A (1-3) above are met
2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least1 week.

II. Fecal Incontinence

A. A *trial period* of sacral nerve neuromodulation with either a percutaneous nerve stimulation or a *temporarily implanted* lead may be considered **medically necessary** in patients with fecal incontinence who meet **all** of the following criteria (II.A.1-4):

1. There is a diagnosis of chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth
2. There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy)
3. The 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
4. Incontinence is not related to another neurologic condition.

B. *Permanent implantation* of a sacral nerve neuromodulation device may be considered **medically necessary** in patients with fecal incontinence who meet **all** of the following

criteria:

1. All of the criteria in II. A (1-4) above are met

2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least1 week.

III. Sacral nerve neuromodulation for the treatment of all other indications is considered **investigational**, including but not limited to the following:

A. Chronic constipation

B. Chronic pelvic pain

C. Stress incontinence

D. Urge incontinence due to a neurologic condition including but not limited to:

1. Detrusor hyperreflexia

2. Multiple sclerosis

3. Spinal cord injury

4. Diabetes with peripheral nerve involvement

E. Other types of chronic voiding dysfunction

SCIENTIFIC EVIDENCE[1]

Literature Appraisal

Assessment of the safety and efficacy of sacral nerve modulation (SNM) requires large, blinded, long-term randomized controlled trials to determine whether 1) the benefits of SNM outweigh any risks, and 2) whether SNM offers advantages over conventional conservative treatments. The appropriate control group(s) against which SNM should be compared is sham stimulation, on- versus off-phases in which patients act as their own controls, or conventional conservative therapies.

Urge Incontinence

Randomized Controlled Trials

- Initially, the policy for SNM as a treatment of urge incontinence was based on a 1998 BlueCross BlueShield Association Technology Evaluation Center (TEC) assessment.[2] A multicenter, randomized controlled clinical trial, conducted as part of the FDA approval process, concluded that SNM reduced urge incontinence compared with control patients.[3]
- 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. However, due to the protocol that selected patients who were likely to benefit based on the peripheral nerve evaluation test, this magnitude of effect is overestimated relative to the total pool of patients with refractory urge incontinence. On the other hand, this screening step avoids an invasive procedure and implantation of the SNM device in patients who are less likely to benefit, thus reducing morbidity and unnecessary treatment.

- An additional prospective randomized controlled trial of 44 patients with urge incontinence became available after the 1998 Assessment.[4] At six months, the implant group showed significantly greater improvement on standardized clinical outcomes as compared to those receiving conservative therapy. The magnitude of effect was substantial. This study provides further evidence of the beneficial effect of SNM for urinary urge incontinence. Brazzelli and colleagues performed a review of articles published between 1966 and 2003 which included four randomized controlled trials and 30 case series.[5] The authors reported that about 80% of patients in the randomized trials achieved continence or greater than 50% improvement in their main incontinence symptoms after SNS compared with about 3% of controls receiving conservative treatments. The case series, which were larger but methodically less reliable, showed similar results. Benefits were reported to persist 3 to 5 years after implantation. The authors noted that technical changes over time were associated with decreased complication rates.

Nonrandomized Studies

A 2011 series by Groen and colleagues in reported the longest follow-up.[6] A total of 60 patients had at least 5 years of follow-up after SNM for refractory idiopathic urge urinary incontinence. Success was defined as at least a 50% decrease in the number of incontinent episodes or pads used per day. The success rate was 52 of 60 (87%) at 1 month and gradually decreased to 37 (62%) at 5 years. The number of women who were completely continent was 15 (25%) at 1 month and 9 (15%) at 5 years. At the 5-year follow-up, SNM was still used by 48/60 (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.

Urinary Urgency/Frequency

Technology Assessment

Initially, the policy for SNM as a treatment of urgency/frequency was based on a 2000 TEC Assessment which included one published randomized controlled trial, a long-term single-arm cohort study, and additional data submitted to the FDA as part of the approval process.[7]

Randomized study
In the multicenter randomized clinical study of 581 patients with a variety of urinary dysfunctions, 220 had significant urgency-frequency symptoms. After 6 months of SNM therapy, 83% of patients with urgency-frequency symptoms reported increased voiding volumes with the same or reduced degree of frequency. At 12 months, 81% of patients had reached normal voiding frequency. Compared to a control group, patients with implants reported significant improvements in quality of life, as evaluated by the SF-36 health survey.

Nonrandomized Studies

There has also been interest in the use of sacral nerve neuromodulation as a treatment of interstitial cystitis, a condition characterized by painful urinary urgency and frequency.[8-10] These studies reported a decrease in both urgency/frequency and pain. These patients would be considered candidates for sacral neuromodulation therapy based on the presence of urgency and frequency alone.

Urinary Retention

Systematic Review

A 2009 Cochrane review[11] described 8 randomized studies on implanted devices for urinary storage and voiding dysfunction in adults. 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." The authors 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.

Randomized controlled trial

In the randomized clinical study submitted to the FDA as part of the approval process, 177 of 581 patients had urinary retention.[12] 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 post-implant, 61% of patients had eliminated the use of catheterization. Patients with implants also reported improved quality of life.

Conclusions: Data from RCTs and case series with long-term follow-up provides sufficient evidence to conclude that sacral nerve neuromodulation is effective and safe in selected patients with urge incontinence, urgency-frequency syndrome, and non-obstructive urinary retention.

Fecal Incontinence

Systematic Review/Meta-analysis

- A Cochrane review reported on three cross-over studies, two for fecal incontinence (n=34 and n=2, respectively) and one for constipation (n=2).[13] This very limited evidence suggested that sacral nerve stimulation can improve continence in selected patients; however, it also reported that temporary, percutaneous stimulation for a 2-3 week period did not always successfully identify patients most likely to benefit from the stimulation. The authors concluded that larger, good quality randomized crossover trials are needed.
- In 2011, Maeda and colleagues published a systematic review of studies on complications following permanent implantation of a SNS device for fecal incontinence and constipation.[14] The authors identified 94 articles. The vast majority of studies addressed fecal incontinence. A combined analysis of data from 31 studies on SNS for fecal incontinence reported a 12% suboptimal response to therapy (149 of 1,232 patients). A review of complications reported in the studies found that the most commonly reported complication was pain around the site of implantation, with a pooled rate of13% (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.

- In 2011, Tan and colleagues published a meta-analysis of randomized trials and observational studies published between 2000 and 2008 on SNS for treating fecal incontinence.[15] 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 SNS. Only one of these studies was an RCT; this was the study by Tjandra and colleagues, discussed earlier.[16] In the 34 studies, a total of 944 patients underwent temporary SNS and 665 subsequently underwent permanent SNS implantation. There were 279 patients who did not receive permanent implantation, and 154 of these were lost to follow-up. Follow-up in the studies ranged from 2 weeks to 35 weeks. In a pooled analysis of findings of 28 studies, there was a statistically significant decrease in incontinence episodes per week with SNS compared to maximal conservative therapy (weighted mean difference: -6.83; 95% confidence interval [CI]:-8.05 to -5.60, $p<0.001$). Fourteen studies reported incontinence scores, and when these results were pooled, there was also a significantly greater improvement in scores with SNS compared to conservative therapy (weighted mean difference: -10.57, 95% CI:-11.89 to -9.24, $p<0.001$).

Randomized Controlled Trials

- Only two randomized, trials were found in the current published literature. A small (n=27) randomized crossover trial of sacral nerve stimulation reported decreased episodes of fecal incontinence and improved quality of life.[17] This study is under-powered and, thus, precludes conclusions.
- In another study, 120 patients with fecal incontinence were randomized to either a treatment group which received sacral nerve stimulation (n=60) or a control group which received non-operative treatment (n=60).[16] The treatment group had a significant decrease in episodes of incontinence and increased quality of life scores while the control group had no significant improvement in these measures. Additional studies are needed to confirm these results and also to better define patient selection criteria.

Nonrandomized studies

- In 2013, Hull et al. reported outcomes in 72 patients (60% of the 120 implanted patients) who had completed a 5-year follow-up visit.[18] Sixty-four (89%) of the patients who contributed bowel diary data at 5 years had at least a 50% improvement from baseline in weekly incontinent episodes and 26 of the 72 patients (36%) had achieved total continence. It is uncertain whether outcomes differed in the 40% of patients who were missing from the 5-year analysis.
- Mellgren et al. reported on the long-term effectiveness and safety of sacral nerve stimulation for fecal incontinence in a large prospective multicenter study.[19] One hundred thirty-three patients underwent test stimulation with a 90% success rate. Mean length of follow-up was 3.1 (range, 0.2-6.1) years, with 83 patients completing all or part of the 3-year follow-up assessment. At 3 years follow-up, 86% of patients ($P < .0001$) reported $\geq$ 50% reduction in the number of incontinent episodes per week compared with baseline and the number of incontinent episodes per week decreased from a mean of 9.4 at baseline to 1.7. Perfect continence was achieved in 40% of subjects. Sacral nerve stimulation had a positive impact on the quality of life. There were no reported unanticipated adverse device effects associated with sacral nerve stimulation therapy.
- In 2011, Maeda and colleagues in Denmark published a retrospective review of prospectively collected data from 176 patients who underwent permanent SNS for fecal incontinence.[20] A total of 245 patients had initially undergone temporary stimulation. The review focused on reportable events, defined as suboptimal outcomes (lack of or loss of efficacy) or adverse events. At the time of data collection, a median of 47 months had elapsed since implantation of

InterStim (n=106) and 21 months in patients implanted with InterStim II (n=70). A total of 592 reportable events were identified in 150 of the 176 (85.2%) patients after a median of 11 months using the implantable devices. Overall, interventions were able to successfully resolve 63 of 212 events (30%).

- Michelsen et al. reported on the outcome of percutaneous nerve evaluation tests and sacral nerve stimulation for the treatment of fecal incontinence from a single center covering a period of 6 years.[21] A total of 177 patients with fecal incontinence underwent a percutaneous nerve evaluation test. Of these patients, 142 (80%) had a positive test, including 21 of 25 (84%) patients who required a repeat percutaneous nerve evaluation test. Because of a functional failure, 16 patients underwent a revision of the permanent electrode. Of 126 patients, 15 (12%) have undergone an explantation, with an infection rate of only 1.6%. Overall, after a median follow-up of 24 (range, 3-72) months, the median Wexner incontinence score decreased from 16 (range, 6-20) to 10 (range, 0-20) ($P < .0001$).
- In 2010, Wexner and others, determined the safety and efficacy of sacral nerve stimulation.[22] A total of 133 patients underwent test stimulation with a 90% success rate, and 120 (110 females) of a mean age of 60.5 years and a mean duration of FI of 6.8 years received chronic implantation. Mean follow-up was 28 (range, 2.2-69.5) months. At 12 months, 83% of subjects achieved therapeutic success (95% confidence interval: 74%-90%; $P < 0.0001$), and 41% achieved 100% continence. Therapeutic success was 85% at 24 months. 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. There were no reported unanticipated adverse device effects associated with InterStim Therapy.
- Numerous small case series (n = 10-40) report the experiences of patients with fecal incontinence who were treated with sacral neuromodulation as an alternative to anal sphincter surgery.[23-32] These series included patients with a variety of etiologies of fecal incontinence, including obstetric injury, spinal cord injury, prior surgery, or idiopathic incontinence. In addition, the range of follow-up periods within each study was very wide (e.g., 2 months– 9.5 years). Thus, it is difficult to determine the complication rates or the durability of any benefits initially reported.

Conclusions: With longer term results from 1 randomized controlled trial with 120 patients, prospective case series and a pooled analysis of data from the RCT and observational studies, evidence is considered sufficient to conclude that sacral nerve neuromodulation/stimulation improves outcomes when used for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy.

Constipation

Systematic review

In 2013, Thomas and colleagues published a systematic review of controlled and uncontrolled studies evaluating sacral nerve stimulation for treatment of chronic constipation.[33] The authors identified 11 case series and 2 blinded cross-over studies. Sample sizes in the case series ranged from 4 to 68 patients implanted with a permanent SNS device; in 7 of the 11 studies, fewer than 25 patients underwent SNS implantation. Among the 2 cross-over studies, one included 2 patients implanted with an SNS device.

Randomized study

In a 2012 study by Knowles and colleagues, temporary stimulation was evaluated in 14 patients.[34] Patients were included if they were diagnosed with evacuatory dysfunction and rectal hyposensitivity and had failed maximal conservative treatment. Patients were randomized to 2 weeks of stimulation with

the SNS device turned on and 2 weeks with the SNS device turned off, in random order. There was no wash-out period between treatments. The primary efficacy outcome was change in rectal sensitivity and was assessed using 3 measures of rectal sensory thresholds. The study found a statistically significantly greater increase in rectal sensitivity with the device turned on in 2 of the 3 measures. Among the secondary outcome measures, there was a significantly greater benefit of active treatment on the percentage of successful bowel movements per week and the percentage of episodes with a sense of complete evacuation. In addition to its small sample size, the study was limited by the lack of a wash-out period between treatments i.e., there could have been a carry-over effect when the device was used first in the "on" position. Moreover, the authors noted that the patients were highly selected; only 14 of the approximately 1800 patients approached met the eligibility criteria and agreed to participate in the study.

Nonrandomized studies

- In 2010, Maeda and colleagues published a retrospective review of 38 patients with constipation who received permanent SNS after a successful trial period.[35] The study focused on reportable events, defined as suboptimal outcomes (lack of or loss of efficacy) or adverse events. The authors did not report detailed criteria for temporary or permanent placement of an SNS device. At the time of chart review, a mean of 25.7 months had elapsed since implantation. A total of 58 reportable events were identified in 22 of the 38 (58%) patients. A median of 2 (range 1-9) events per patient were reported; 26 of 58 events (45%) were reported in the first 6 months after device implantation. The most common reportable events were lack or loss of efficacy (26 of 58 events, 45%), and pain (16 events, 28%). Twenty-eight (48%) of the events were resolved by reprogramming. Surgical interventions were required for 19 (33%) of the events, most commonly permanent electrode replacement (14 events). Three of 38 (8%) patients discontinued use of the device due to reportable events.
- In 2010, Kamm and colleagues published findings on a prospective study that included patients who failed conservative treatment for intractable idiopathic constipation and underwent 21 days of test stimulation [36] Sixty-two patients who had idiopathic chronic constipation lasting at least 1 year and had failed medical and behavioral treatments were included. Forty-five of the 62 (73%) met criteria for permanent implantation during the 3-week trial period. After a median follow-up of 28 months (range 1-55 months) after permanent implantation, 39 of 45 (87%) patients were classified as treatment successes (i.e., met same improvement criteria as were used to evaluate temporary stimulation). There was a significant increase in the frequency of bowel movements from a median of 2.3 per week at baseline to 6.6 per week at latest follow-up ($p<0.001$). The frequency of spontaneous bowel movements (i.e., without use of laxatives or other stimulation) increased from a median of 1.7 per week at baseline to 4.3 per week at last follow-up; $p=0.0004$. A total of 101 adverse events were reported; 40 (40%) of these were attributed to the underlying constipation or an unrelated diagnosis. Eleven serious adverse events related to treatment were reported (the authors did not specify whether any patients experienced more than 1 serious event). The study has been criticized for including a large number of patients who had more than 2 bowel movements per week at study entry.
- Several small case series were identified that focused on patients with slow transit constipation.[30,37,38] While promising results were reported, these case series are inadequate to permit scientific conclusions due to methodological limitations such as lack of lack of randomization and blinding, and lack of an adequate comparison group.

Conclusions: Only 2 small controlled studies are available, both cross-over studies; 1 had only 2 patients and the other had methodological limitations. In addition, there are several, mainly small, case series.

This represents insufficient evidence to permit scientific conclusions about the efficacy and safety of sacral nerve neuromodulation/stimulation for patients with constipation.

Chronic Pelvic Pain

Systematic Review

Tirlapur et al. assessed the effectiveness of tibial and sacral nerve stimulation in the treatment of bladder pain syndrome (BPS) and chronic pelvic pain (CPP).[39] Authors included randomized and prospective quasi-randomized controlled studies vs. sham nerve stimulation treatment or usual care of patients with CPP and BPS who underwent sacral or tibial nerve stimulation were included. Three studies with 169 patients treated with tibial nerve stimulation were included; two for CPP and one for BPS. There were improvements in pain, urinary and quality of life scores. There were no reported data for sacral nerve stimulation. There is scanty literature reporting variable success of posterior tibial nerve stimulation in improving pain, urinary symptoms and quality of life in CPP and BPS. Authors concluded that due to the quality of the literature, a large multi-centered clinical trial investigating the effectiveness of electrical nerve stimulation to treat BPS and CPP is recommended.

Nonrandomized studies

Several case series have evaluated sacral neuromodulation for treating chronic pelvic pain. For example, in 2012 Martelluci and colleagues reported on 27 patients with chronic pelvic pain (at least 6 months) who underwent testing for SNM implantation[40]. After a 4-week temporary stimulation phase, 16 of 27 patients (59%) underwent implantation of an Interstim device. In the 16 implanted patients, mean pain on a visual analogue scale (VAS) was 8.1 prior to implantation and 2.1 at the 6- and 12-month follow-ups. An earlier study by Siegel and colleagues reported on 10 patients and stated that 9 of the 10 experienced a decrease in pain with SNS stimulation. [41]

Conclusions: Data from several small case series with heterogenous patients represents insufficient evidence that sacral nerve neuromodulation/stimulation is safe and effective for treating chronic pelvic pain.

Clinical Practice Guidelines

Practice Guidelines from the American College of Gastroenterology (ACG) in 2004 on the diagnosis and management of fecal incontinence found limited evidence in favor of sacral nerve stimulation.[42] The ACG concluded that the precise indication for SNM, its comorbidity, long-term outcome, and efficacy remain to be defined.

In 2004 (reaffirmed 2008), the American College of Obstetricians and Gynecologists (ACOG) recommended that sacral nerve stimulation be considered as a treatment option for chronic pelvic pain.[43] This was rated a Level B recommendation, meaning that it was based on limited or inconsistent scientific evidence.

Summary

The current evidence is sufficient to conclude that sacral nerve neuromodulation/stimulation (SNM) improves health outcomes and quality of life in select patients with urinary urge or urgency-frequency

incontinence, non-obstructive urinary retention, and fecal incontinence. Therefore, SNM may be considered medically necessary for these conditions when criteria are met.

The current evidence is insufficient to permit conclusions on the effectiveness and safety of sacral nerve neuromodulation/stimulation (SNM) as a treatment for conditions other than urinary urge or urgency-frequency incontinence, non-obstructive urinary retention, and fecal incontinence. Therefore, SNM is considered investigational for other conditions, including but is not limited to chronic constipation, chronic pelvic pain, urinary stress incontinence, or urge incontinence due to neurologic conditions such as multiple sclerosis, spinal cord injury, diabetes-related peripheral nerve conditions, and detrusor hyperreflexia.

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Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, Allied Health, Policy No. 4

Transanal Radiofrequency Treatment of Fecal Incontinence, Surgery, Policy No. 129

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence, Surgery, Policy No. 130

Posterior Nerve Stimulation for Voiding Dysfunction, Surgery, Policy No. 154

CODES	NUMBER	DESCRIPTION
CPT	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
	64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)

CODES	NUMBER	DESCRIPTION
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling.
	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
	95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95971	simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
	95972	complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
	95973	complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour
HCPCS	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

CODES	NUMBER	DESCRIPTION
	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