# Sacral nerve modulation/stimulation

Clinical Policy ID: CCP.1522

Recent review date: 2/2026

Next review date: 6/2027

Policy contains: Overactive bladder syndrome; sacral nerve stimulation; urinary incontinence; fecal incontinence.

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## Coverage policy

Sacral nerve stimulation (or sacral neuromodulation) is clinically proven and, therefore, may be medically necessary for members ages 18 and older with severe, refractory overactive bladder syndrome, nonobstructive urinary retention, and urgency urinary incontinence when both criteria are met (American Urological Association [Cameron, 2024; Ginsberg, 2021]; International Continence Society [Goldman, 2018]; National Institute for Health and Care Excellence, 2015):

- A percutaneous stimulation test to determine candidacy for a permanent implantation demonstrates at least a 50% reduction in incontinence symptoms as documented in voiding diaries.
- More conservative first- and second-line approaches are ineffective, not tolerated, refused, or contraindicated, and the member is willing to undergo a surgical procedure.

Sacral nerve stimulation is investigational/not clinically proven and, therefore, not medically necessary as a treatment for stress urinary incontinence (American Urological Association [Kobashi, 2023]).

Sacral nerve stimulation is clinically proven and, therefore may be medically necessary as a treatment for members ages 18 and older with fecal incontinence (Joint European guideline [Assmann, 2022]; American Society of Colon and Rectal Surgeons [Bordeianou, 2023]):

- A percutaneous stimulation test to determine candidacy for a permanent implantation demonstrates at least a 50% reduction in fecal incontinence episodes as documented in bowel diaries.
- More conservative first- and second-line approaches are ineffective, not tolerated, refused, or contraindicated, and the member is willing to undergo a surgical procedure.

Limitations

All other uses of sacral nerve stimulation are investigational/not clinically proven and, therefore, not medically necessary.

> NOTE: sacral nerve stimulation may be considered in developmentally appropriate pediatric members with constipation, who have failed an extended period of behavioral modification, biofeedback, and pharmacologic therapy, before irreversible surgery is considered (International Continence Society [Goldman, 2018]).

Absolute contraindications to sacral nerve stimulation include (Goldman, 2018):

- Inadequate clinical response to a therapeutic trial.
- Inability to operate the device with lack of supportive caregivers who could otherwise offer assistance.
- Pregnancy.

Relative contraindications include (Ginsberg, 2021; Goldman, 2018):

- Progressive neurologic disease.
- Established complete spinal cord injury or spina bifida.
- A known anticipated need for magnetic resonance imaging of body parts below the head.
- An abnormal sacral anatomy.

Alternative covered services

- Pharmacotherapy.
- Behavioral modification.
- Pelvic floor muscle training.
- Bladder training.
- Anterior colporrhaphy with bladder neck (Kelly-Kennedy) plication.
- Retropubic suspension (e.g., retropubic urethropexy or Burch procedure).
- Sling procedures (e.g., pubovaginal or suburethral sling, midurethral sling [transvaginal tapes, transobturator slings], bulbourethral sling).
- Artificial urinary sphincter implantation.
- Periurethral bulking injections.
- Intradetrusor onabotulinumtoxinA (Botox) injection.
- Peripheral tibial nerve stimulation.
- Non-implantable pelvic floor electrical stimulator.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

## Background

Pelvic floor dysfunction refers to an array of symptoms and anatomic changes related to abnormal function of the pelvic floor muscles. The causes of pelvic floor dysfunction are not well understood, but a variety of urologic, gynecologic, and colorectal conditions produce symptoms of pelvic floor dysfunction. The most common symptoms are constipation, incontinence, and pain (Grimes, 2023).

Treatments are tailored to the patient's need and are often multidisciplinary in nature. Lifestyle modifications, pharmaceuticals, manipulation (e.g., splinting, pessary, physical therapy, and biofeedback), minimally invasive procedures, and surgery may be indicated. Sacral nerve modulation represents a minimally invasive approach to treating certain pelvic floor disorders. It involves the placement of electrical stimulation targeting one of the S3 foramina with the goal of restoring proper signaling to the brain (Grimes, 2023).

Multiple devices have received FDA premarket approval (PMA) for sacral neuromodulation:

- InterStim™ system (Medtronic, Inc., Minneapolis, Minnesota) approved for urinary urge incontinence (1997), overactive bladder symptoms and nonobstructive urinary retention (1999), and fecal incontinence (2011). Sacral neuromodulation therapy includes a test stimulation phase prior to permanent implantation in appropriate candidates. Current generation devices (InterStim X, InterStim Micro) have device lives of 10 to 15 or more years (U.S. Food and Drug Administration, PMA P970004).
- Axonics® Sacral Neuromodulation System (Boston Scientific Corp., Marlborough, Massachusetts) approved for urinary urge incontinence, urgency-frequency, and urinary retention (PMA P180046; November 13, 2019) and for fecal incontinence (PMA P190006; September 6, 2019). It is a miniaturized, rechargeable device designed to deliver therapy for at least 15 years.
- VIRTIS™ Sacral Neuromodulation System (Cirtec Medical Corporation, Brooklyn Park, Minnesota) approved for urinary retention and overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination. It requires a two-stage trial and permanent implantation process and has an average device life of 10 years (U.S. Food and Drug Administration, 2023).
- Neuspera Sacral Neuromodulation System (Neuspera Medical Inc., San Jose, California) approved for urinary urge incontinence (PMA P240031; June 17, 2025). The system uses a miniaturized, passive implant without a battery; it is powered and controlled externally.

## Findings

The evidence supporting sacral nerve stimulation encompasses professional society guidelines, systematic reviews, meta-analyses, and observational studies spanning both urinary and bowel dysfunction. Collectively, the literature establishes sacral nerve stimulation as a safe and effective treatment option for adults with refractory overactive bladder, nonobstructive urinary retention, and fecal incontinence who have not responded to conservative management. Guidelines consistently position sacral nerve stimulation as a third-line intervention, recommended only after behavioral therapies and pharmacologic treatments have proven ineffective, intolerable, or contraindicated. The evidence does not support sacral nerve stimulation for stress urinary incontinence or constipation in adults. Pediatric applications remain off-label, with limited evidence suggesting potential benefit in carefully selected individuals with refractory conditions.

Guidelines

Professional society guidelines uniformly recommend reserving sacral nerve stimulation for individuals who have failed conservative management. According to the International Continence Society, sacral nerve stimulation is not indicated as a first-line therapy for either urinary or bowel disorders; rather, it should be reserved for cases of refractory urinary urgency and frequency, urgency urinary incontinence, nonobstructive urinary retention, and fecal incontinence (Goldman, 2018).

individualsindividualsFor overactive bladder, the American Urological Association recommends offering minimally invasive procedures to individuals who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies. Sacral nerve stimulation is recommended for individuals with overactive bladder who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy, as an alternative to percutaneous tibial nerve stimulation or intradetrusor botulinum toxin injection (Cameron, 2024). For adults with neurogenic lower urinary tract dysfunction, the American Urological Association conditionally recommends sacral nerve stimulation for urgency, frequency, or urgency incontinence, excluding individuals with spinal cord injury or spina bifida. These recommendations are based on limited evidence from single-center cohort studies suggesting some efficacy, though further studies are needed (Ginsberg, 2021). The National Institute for Health and Care Excellence states that sacral nerve stimulation can be considered for chronic nonobstructive urinary retention as an alternative to surgical urinary diversion procedures, given the limited efficacy of drug therapy and urethral dilation (National Institute for Health and Care Excellence, 2015).

Sacral nerve stimulation is not approved by the United States Food and Drug Administration for stress urinary incontinence, and evidence supporting its use for this indication is limited. For off-label uses, there is limited evidence supporting safety and efficacy in individuals with interstitial cystitis or bladder pain syndrome, and no evidence supports its use in individuals without interstitial cystitis who have chronic pelvic pain (Goldman, 2018).

Guidelines for bowel dysfunction follow a similar stepwise approach. First-line treatments for fecal incontinence include lifestyle adjustments, dietary advice, basic behavioral modification, stool bulking agents or antidiarrheal medication, pelvic floor muscle exercises, and absorbent products for containment. Second-line nonsurgical interventions include percutaneous or transcutaneous posterior tibial nerve stimulation, transanal irrigation, and anal inserts. The American Society of Colon and Rectal Surgeons conditionally recommends sacral nerve stimulation as a first-line surgical option for fecal incontinence in individuals with or without sphincter defects (Bordeianou, 2023). A joint European guideline developed by the United European Gastroenterology, European Society of Coloproctology, European Society of Neurogastroenterology and Motility, and the European Society for Primary Care Gastroenterology states that sacral nerve stimulation could be considered in individuals with fecal incontinence and an unsatisfactory treatment response to first- and second-line nonsurgical options (Assmann, 2022).

Guidelines addressing pediatric populations emphasize the off-label nature of sacral nerve stimulation in this age group. The European Association of Urology does not recommend sacral nerve stimulation for overactive bladder in children outside of clinical trials. While an initial positive response may be achieved, the procedure is associated with a high recurrence rate requiring long-term follow-up, and other forms of lower urinary tract dysfunction may emerge in adulthood (Radmayr, 2024). For bowel dysfunction, the International Continence Society recommends consideration of sacral nerve stimulation in children with constipation who have failed an extended period of behavioral modification, biofeedback, and pharmacologic therapy, before irreversible surgery is considered. The Society acknowledges that safety and effectiveness have not been established for pediatric indications (Goldman, 2018).

individualsindividualsContraindications to sacral nerve stimulation are well established. Absolute contraindications include inadequate clinical response to a therapeutic trial, inability to operate the device with lack of supportive caregivers who could otherwise offer assistance, and pregnancy. Relative contraindications include severe or rapidly progressive neurologic disease, established complete spinal cord injury or spina bifida, and abnormal sacral anatomy. Magnetic resonance imaging compatibility depends on the implanted system and components; clinicians should consult device-specific labeling for conditional scanning conditions (Goldman, 2018; Ginsberg, 2021).

Systematic reviews

Systematic reviews evaluating sacral nerve stimulation for urinary dysfunction demonstrate consistent evidence of efficacy in appropriately selected individuals. For chronic nonobstructive urinary retention, a systematic review comparing sacral nerve stimulation to percutaneous tibial nerve stimulation using the contemporary percutaneous tined lead implantation technique found that sacral nerve stimulation compares favorably. The long-term success rate for percutaneous tibial nerve stimulation was substantially lower than that for sacral nerve stimulation, at 50 to 60 % versus 65.5 to 100 %. Revision and explantation rates for sacral nerve stimulation were generally less than 20 % (Ho, 2021).

In children with nonneurogenic overactive bladder, a systematic review of 14 low-quality studies found consistently positive results with improved outcomes and few adverse effects, although a complete response may not be achieved. The limitations of the evidence include a dearth of long-term outcomes and heterogeneity in reporting, as there is no standard protocol for the pediatric population (Casal Beloy, 2021).

For bowel dysfunctionindividuals, a Cochrane review of six crossover trials and two parallel group trials found that sacral nerve stimulation improved continence in a proportion of individuals with fecal incontinence but did not improve symptoms in individuals with constipation. The causes of fecal incontinence were idiopathic, neurogenic, and complications from anorectal surgery. Adverse events were reported inconsistently, but common complaints were pain or infection at the implantation site and urological symptoms. Most adverse events were resolved with adjustments to the stimulator or leads, or explantation. Two trials included individuals with constipation with mixed efficacy results. Rigorous high-quality randomized trials are needed to improve the certainty in the findings (Thaha, 2015).

A systematic review examining long-term outcomes from 36 nonrandomized studies enrolling 3,700 individuals demonstrated durable improvement exceeding 36 months following sacral nerve stimulation, based on patient diary entries and validated instruments measuring fecal incontinence severity. Adverse events were reported inconsistently, but the overall revision rate was 35.2 % and the explantation rate was 19.7 % (Eggers, 2024).

Two systematic reviews evaluated sacral nerve stimulation for Low Anterior Resection Syndrome, which refers to bowel dysfunction symptoms that can occur following a low anterior rectal resection procedure, typically for treating rectal cancer. Both reviews found limited but encouraging evidence supporting sacral nerve stimulation to improve symptoms and quality of life (Ram, 2020). Fecal incontinence was reduced by an average of 67 % (Huang, 2019).

Systematic reviews in pediatric populations with bowel dysfunction show variable but generally positive results. One systematic review found that sacral nerve stimulation produced varying degrees of effectiveness in improving bowel movements per day, transit times, and soiling in children (Dewberry, 2019). Another review reported that sacral nerve stimulation reduced constipation in children by 79 to 86 % but had a complication rate of 17 to 50 % (Iacona, 2019).

Meta-analyses

Meta-analyses provide quantitative synthesis of the comparative efficacy and safety of sacral nerve stimulation relative to other treatments. A systematic review and meta-analysis evaluating sacral nerve stimulation and implantable tibial neuromodulation for overactive bladder found that sacral nerve stimulation offers a safe and effective alternative for adults with overactive bladder or nonobstructive urinary retention unresponsive to conservative measures. The analysis demonstrated significant improvement in symptom response rates and quality of life, with relatively low rates of procedure- and device-related adverse events (Amundsen, 2024).

A network meta-analysis of randomized controlled trials comparing neuromodulation technologies for overactive bladder in adults found that sacral nerve stimulation may produce a clinically significant reduction in urgency urinary incontinence episodes in some individuals (Huang, 2023). For neurogenic bladder, a meta-analysis evaluating effectiveness and safety demonstrated favorable outcomes with sacral nerve stimulation (Wei, 2023).

Comparative analyses of sacral nerve stimulation and botulinum toxin injection provide important evidence for treatment sequencing. A meta-analysis of seven nonrandomized studies enrolling 319 individuals found no differences in outcomes when sacral nerve stimulation was performed with or without prior botulinum toxin therapy. The success rate after failed botulinum toxin therapy was 58.5 % (95 % confidence interval 0.47 to 0.70), similar to that of individuals who chose sacral nerve stimulation as first-choice therapy. The mean duration of botulinum toxin treatment varied from 11.8 to 23 months among studies (Yang, 2020).

A 2025 systematic review and meta-analysis of 12 studies (n = 2,645) participants comparing onabotulinumtoxinA and sacral nerve stimulation for refractory overactive bladder found a mixed comparative profile. OnabotulinumtoxinA was favored for achieving at least 75 % reduction in urgency urinary incontinence episodes (odds ratio 0.41, 95 % confidence interval 0.30 to 0.58), while sacral nerve stimulation was favored for complete resolution of urgency urinary incontinence (odds ratio 7.84, 95 % confidence interval 3.93 to 15.64) and lower urinary tract infection risk (odds ratio 0.30, 95 % confidence interval 0.22 to 0.42). No significant difference was found for achieving at least 50 % reduction in urgency urinary incontinence episodes (Roman, 2025).

For fecal incontinence, a 2025 systematic review and meta-analysis of 10 studies (n= 779) participants. evaluated sacral nerve stimulation specifically in individuals with anal sphincter defects. The pooled continence improvement rate was 66.7 % (95 % confidence interval 52.2 % to 81.1 %), with a weighted mean reduction in incontinence scores of 8.53 points (95 % confidence interval 6.11 to 10.96). The pooled complication rate was 18.5 % and the device removal rate was 9.1 %. Meta-regression found less improvement associated with prior sphincteroplasty, external anal sphincter defects greater than 120 degrees, and low resting anal pressure. In a subset of four studies comparing sacral nerve stimulation to anal sphincteroplasty, sacral nerve stimulation was associated with significantly higher odds of continence improvement (odds ratio 1.68, 95 % confidence interval 1.16 to 2.44) with similar complication rates. The authors concluded that anal sphincter defects are not a contraindication to sacral nerve stimulation .

Other evidence

Real-world evidence and observational studies complement the findings from systematic reviews and meta-analyses. An analysis of statewide data in New York enrolling 2,680 individuals showed that individuals with overactive bladder who received onabotulinumtoxinA therapy were at higher risk for urinary tract infection, hematuria, urinary retention, and emergency room visits compared to those treated with sacral nerve stimulation. Sacral nerve stimulation implantation led to reintervention in 15.8 % of cases within one year and in 26.1 % at three years. The overall cost of onabotulinumtoxinA treatment was lower than that of sacral nerve stimulation treatment ($2,896 versus $3,454 at one year; $15,343 versus $16,189 at three years) (Chughtai, 2020).

A retrospective cohort study of 70 children with a median age of 12.8 years who had medically refractory fecal incontinence or severe constipation provides evidence supporting earlier systematic review findings in pediatric populations. The most common diagnoses were idiopathic constipation (67.1 %) and anorectal malformation (15.7 %). Prior treatment consisted of oral therapy, an enema regimen, or a combination of both. The median follow-up time after stimulator placement was 2.3 years. Sacral nerve stimulation placement produced significant improvement in the rate of daytime and nighttime involuntary bowel movements, the rate of daytime and nighttime fecal continence, and the rate of at least weekly fecal incontinence. Minor pain or neurological symptoms occurred in 40 % of individuals, and wound infection occurred in 5.7 %. Additional surgery was required in 40 % of individuals, of whom 17 required revision for lead malfunction or battery replacement. Eleven individuals required explantation, six of whom chose no replacement for reasons related to surgical site infection, minimal efficacy, good function achieved without stimulation, or preference for ileostomy. The estimated median time to reoperation was approximately 5.2 years (Trinidad, 2023).

In 2026, we reorganized the findings section and added a new systematic review (Roman, 2025). No policy changes were warranted.

## References

On ~~January 10, 2025~~January 8, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “sacral neuromodulation,” “sacral nerve stimulation,” “electric nerve stimulation (MeSH),” “overactive bladder,” and “incontinence.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.


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## Policy updates

2/2023: initial review date and clinical policy effective date: 3/2023

2/2024: Policy references updated.

2/2025: Policy references updated. Coverage modified.

2/2026: Policy references updated.

## Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1522. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

| Code | Code Description |
|---|---|

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|---|---|
| | **CPT Category I - Surgical Procedures** |
| 64561 | Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement), including image guidance, if performed |
| 64581 | Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) |
| 64585 | Revision or removal of peripheral neurostimulator electrode array |
| 64590 | Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver |
| 64595 | Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array |
| | **CPT Category I - Electronic Analysis/Programming** |
| 95970 | Electronic analysis of implanted neurostimulator pulse generator; brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, without programming |
| 95971 | Electronic analysis with simple programming (1-3 parameters); spinal cord or peripheral nerve (e.g., sacral nerve) |
| 95972 | Electronic analysis with complex programming (4+ parameters); spinal cord or peripheral nerve (e.g., sacral nerve) |
| | **CPT Category III - Integrated Systems** |
| 0786T | Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance |
| 0787T | Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator |
| 0788T | Electronic analysis with simple programming of implanted integrated neurostimulation system; sacral nerve, 1-3 parameters |
| 0789T | Electronic analysis with complex programming of implanted integrated neurostimulation system; sacral nerve, 4+ parameters |
| | **HCPCS Level II - Hospital Outpatient (C-Codes)** |
| C1767 | Generator, neurostimulator (implantable), non-rechargeable |
| C1778 | Lead, neurostimulator (implantable) |
| C1787 | Patient programmer, neurostimulator |
| C1820 | Generator, neurostimulator (implantable), with rechargeable battery and charging system |
| C1883 | Adaptor/extension, pacing lead or neurostimulator lead (implantable) |
| C1897 | Lead, neurostimulator test kit (implantable) |
| | **HCPCS Level II - Prosthetic Devices (L-Codes)** |
| L8679 | Implantable neurostimulator pulse generator, any type |
| L8681 | Patient programmer (external), replacement only |
| L8682 | Implantable neurostimulator radiofrequency receiver |
| L8684 | Radiofrequency transmitter (external) for sacral root neurostimulator, replacement |
| L8689 | External recharging system for battery (internal), replacement only |
| | **HCPCS - Supplies** |
| A4290 | Sacral nerve stimulation test lead, each |