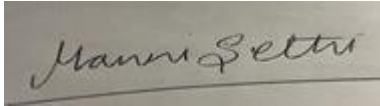


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 3/1/2025										
Policy Number: ccp.1522	Effective Date: 3/2/2023 Revision Date: 2/2025										
Policy Name: Sacral nerve modulation/stimulation											
Type of Submission: Type of Policy: <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 5px;">☐ New Policy</td><td style="width: 50%; padding: 5px;">☒ Prior Authorization Policy</td></tr><tr><td style="padding: 5px;">☒ Revised Policy*</td><td style="padding: 5px;">☐ Base Policy</td></tr><tr><td style="padding: 5px;">☐ Annual Review- no revisions</td><td style="padding: 5px;">☐ Experimental/Investigational Policy</td></tr><tr><td style="padding: 5px;"></td><td style="padding: 5px;">☐ Statewide PDL</td></tr><tr><td style="padding: 5px;"></td><td style="padding: 5px;">☐ Other:</td></tr></table>		☐ New Policy	☒ Prior Authorization Policy	☒ Revised Policy*	☐ Base Policy	☐ Annual Review- no revisions	☐ Experimental/Investigational Policy		☐ Statewide PDL		☐ Other:
☐ New Policy	☒ Prior Authorization Policy										
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	☐ Statewide PDL										
	☐ Other:										
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: Please see tracked changes below.											
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 										

Sacral nerve modulation/stimulation

Clinical Policy ID: CCP.1522

Recent review date: 2/2025

Next review date: 6/2026

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

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania on a case by case basis when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania clinical policies are not guarantees of payment.

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 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 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.

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, including Botox.
- 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).

Three devices have received premarket approval to provide sacral

- InterStim™ system (Medtronic, Inc., Minneapolis, Minnesota) approved for urinary incontinence, overactive bladder, urinary retention, and fecal incontinence. It requires a two-stage trial and permanent implantation process and has a device life of approximately 4.4 years, after which it must be replaced (U.S. Food and Drug Administration, 1997).
- Axonics® r-SNM System (Boston Scientific Corp., Marlborough, Massachusetts) approved for urinary incontinence, overactive bladder, urinary retention, and fecal incontinence. It is a miniaturized, rechargeable device designed to deliver therapy for at least 15 years. The device does not require two steps for implantation. (U.S. Food and Drug Administration, 2019).
- 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).

Findings

Guidelines

According to the International Continence Society (Goldman, 2018), sacral nerve stimulation is not indicated as a first line therapy for either urinary or bowel disorders. It should be reserved for cases of refractory urinary urgency and frequency, urgency urinary incontinence, non-obstructive urinary retention, and fecal incontinence.

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 pregnant patients. Relative contraindications include patients with severe or rapidly progressive neurologic disease, established complete spinal cord injury, a known anticipated need for magnetic resonance imaging of body parts below the head, or an abnormal sacral anatomy (Goldman, 2018).

Urinary dysfunction

The American Urological Association recommends offering minimally invasive procedures to patients with overactive bladder who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies. The American Urological Association recommends sacral nerve stimulation in patients 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).

The American Urological Association does not recommend electrical stimulation therapy for stress urinary incontinence, as the evidence to date is inconsistent and of poor quality and does not suggest superiority to established non-invasive therapies (Kobashi, 2023).

For adults with neurogenic lower urinary tract dysfunction, the American Urological Association conditionally recommends sacral nerve stimulation for urgency, frequency, or urgency incontinence, excluding patients with spinal cord injury or spina bifida. The recommendations are based on limited evidence from single center cohort studies that suggests some efficacy in this population, but further studies are needed (Ginsberg, 2021).

The National Institute for Health and Care Excellence (2015) states sacral nerve stimulation can be considered for chronic nonobstructive urinary retention as an alternative to surgical urinary diversion procedures, in light of the limited efficacy of drug therapy and urethral dilation.

For off-label uses, there is limited evidence supporting safety and efficacy in patients with interstitial cystitis/bladder pain syndrome and no evidence supporting its use in patients with non-interstitial cystitis/bladder pain syndrome chronic pelvic pain (Goldman, 2018).

For pediatric populations, sacral nerve stimulation represents an off-label use. The European Association of Urology does not recommend sacral nerve stimulation for overactive bladder 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).

Bowel dysfunction

For fecal incontinence, first line treatments include lifestyle adjustments, dietary advice, basic behavioral modification, stool bulking agents and/ or anti-diarrheal medication, pelvic floor muscle exercises, absorbent products for containment, and possibly skin care products to treat irritation of the skin around the anus. Second line non-surgical interventions include percutaneous or transcutaneous posterior tibial nerve stimulation, transanal irrigation, and anal inserts for containment purposes. In pediatric populations with fecal incontinence or constipation, sacral nerve stimulation represents an off-label use.

The American Society of Colon and Rectal Surgeons conditionally recommends sacral nerve stimulation as a first-line surgical option for fecal incontinence in patients with or without sphincter defects (Bordeianou, 2023). Members from the United European Gastroenterology, European Society of Coloproctology, European Society of Neurogastroenterology and Motility, and the European Society for Primary Care Gastroenterology developed a joint guideline on the management of fecal incontinence in adults. Sacral nerve stimulation could be considered in patients with fecal incontinence and an unsatisfactory treatment response to first- and second-line non-surgical treatment options (Assmann, 2022).

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).

Evidence review

Urinary dysfunction

Evidence from systematic reviews and meta-analyses consists of nonrandomized studies. Sacral nerve stimulation offers a safe and effective alternative for adults with overactive bladder or nonobstructive urinary retention that is unresponsive to conservative measures. Sacral nerve stimulation resulted in significant improvement in symptom response rates and quality-of-life, and relatively low rates of procedure and device-related adverse events (Amundsen, 2024; Huang, 2023; Wei, 2023). Sacral nerve stimulation may produce a clinically significant reduction in urgency urinary incontinence episodes in some cases (Huang, 2023). Limited evidence involving children with overactive bladder suggests positive results can be achieved (Casal Beloy, 2021).

Notably, limited research found no differences in outcomes when sacral nerve stimulation was performed with or without prior botulinum toxin therapy. Yang's analysis of seven nonrandomized studies (n = 319) reported a success rate after failed botulinum toxin therapy of 58.5% (95% confidence interval 0.47 to 0.70), which was similar to that of patients who chose sacral nerve stimulation as a first choice therapy ($P = .735$). The mean duration of botulinum toxin treatment varied from 11.8 months to 23 months among studies (Yang, 2020).

An analysis of state-wide data in New York ($n = 2,680$) showed patients with overactive bladder who received onabotulinumtoxinA therapy were at higher risk for urinary tract infection, hematuria, urinary retention, and an emergency room visit compared to those treated with sacral nerve stimulation. Sacral nerve stimulation implantation led to re-intervention 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, each $P < .01$) (Chughtai, 2020).

For treatment of chronic nonobstructive urinary retention, sacral nerve stimulation using the contemporary percutaneous tined lead implantation technique compares favorably to percutaneous tibial nerve stimulation. The long-term success rate for percutaneous tibial nerve stimulation was much lower than that for sacral nerve stimulation (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 of sacral nerve stimulation found consistently positive results (improved outcomes with few adverse effects), although a complete response may not be achieved. Limits of the evidence are a dearth of long-term outcomes and heterogeneity in reporting, as there is no standard protocol for the pediatric population (Casal Beloy, 2021).

Bowel dysfunction

Sacral nerve stimulation is a safe and effective treatment for adults with fecal incontinence refractory to non-surgical treatment, reserving direct surgery to the anal sphincter for highly-selected patients or for those in whom sacral nerve stimulation has failed. The evidence is insufficient to support sacral nerve stimulation for constipation. Limited evidence suggests a benefit may be achieved in children with medically refractory fecal incontinence and severe constipation, although this remains an off-label use.

In a Cochrane review of six crossover trials and two parallel group trials, sacral nerve stimulation improved continence in a proportion of patients with fecal incontinence but did not improve symptoms in patients 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 were resolved with adjustments to the stimulator/leads or explantation. Two trials included patients with constipation with mixed efficacy results. Rigorous high quality randomized trials are needed to improve the certainty in the findings (Thaha, 2015).

Evidence from 36 nonrandomized studies ($n = 3,700$) shows durable improvement in outcomes exceeding 36 months following sacral nerve stimulation based on patient diary (number of episodes) and validated instruments to measure 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).

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

In children, a systematic review showed sacral nerve stimulation produced varying degrees of effectiveness in improving bowel movements per day, transit times, and soiling (Dewberry, 2019). In another review, sacral nerve stimulation reduced constipation in children by 79% to 86% but had a complication rate of 17% to 50% (Iacona, 2019).

A retrospective cohort study of 70 children (median age 12.8 years) with medically refractory fecal incontinence or severe constipation supports these earlier findings (Trinidad, 2023). 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 (interquartile range 1.5 to 4.7 years).

Sacral nerve stimulation placement produced a 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 daytime and nighttime fecal incontinence. Minor pain or neurological symptoms occurred in 40% of patients, and wound infection occurred in 5.7%. Additional surgery was required in 28 (40%) of patients, of whom 17 required revision (lead malfunction or battery replacement). Eleven patients required explantation, six of whom chose no replacement, the reasons for which were related to surgical site infection, minimal efficacy, good function achieved without stimulation, and choosing ileostomy. The estimated median time to re-operation was approximately 5.2 years (Trinidad, 2023).

In 2025, we updated the references, reorganized the findings, added several new guidelines, and deleted several older references. We revised coverage to align with new guideline recommendations.

References

On January 10, 2025, 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.

