Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania	**Submission Date**: 3/1/2024
Policy Number: ccp.1522	**Effective Date:** 3/2023 **Revision Date:** February 1, 2024
Policy Name: Sacral nerve modulation/stimulation	

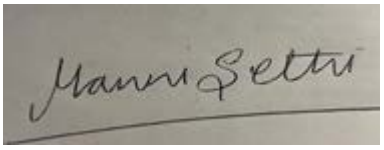
Type of Submission – Check all that apply:

New Policy
X Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

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: 2/2024

Next review date: 6/2025

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' 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 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' 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's 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's clinical policies are not guarantees of payment.

Coverage policy

Sacral nerve stimulation or sacral neuromodulation (e.g., InterStim System, Medtronic, Inc., Minneapolis, Minnesota) is clinically proven and, therefore, may be medically necessary as a third-line treatment option for severe, refractory overactive bladder syndrome and urinary incontinence when all of the following criteria are met (Abrams, 2017; Gormley, 2019):

- Symptoms of incontinence have been present for at least 12 months, resulting in significant disability, such as the limited ability to work or participate in activities outside of the home.
- The incontinence is non-neurologic in nature.
- 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 have been ineffective or are contraindicated, and member is willing to undergo a surgical procedure (see Appendix).

Sacral nerve stimulation or sacral neuromodulation is clinically proven and, therefore, medically necessary as a third-line treatment option for fecal incontinence when the above criteria are met, plus all of the following (Abrams, 2017):

- No rectal surgery has been performed in the past 12 months.
- The condition is not related to anorectal malformations.

Limitations

No limitations were identified during the writing of this policy.

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

Previously referred to as “stress incontinence,” urge incontinence,” or “detrusor instability,” the term “overactive bladder syndrome,” adopted by the International Continence Society, provides a comprehensive and descriptive approach to the condition. The International Continence Society (Haylen, 2010) defines overactive bladder syndrome as:

- Urgency, which is the complaint of a sudden need to void.
- Involuntary loss of urine with urgency symptoms (with or without urge incontinence).
- Usually with increased daytime frequency, often defined as more than eight voids during waking hours, or increased nocturia, which is awakening from sleep to empty the bladder.
- Absence of urinary tract infection or other detectable disease.

Categories of urinary incontinence include total (associated with urinary tract fistula or ectopic ureter), functional (associated with psychiatric or mobility disorders), uncategorized, overflow, post-micturition dribble, radiation therapy incontinence, and climacturia. Urinary incontinence encompasses stress incontinence, urge incontinence, mixed incontinence, total incontinence, and reversible incontinence (Haylen, 2010). While etiology remains elusive, aberrations in neurologic signals from the bladder (sensation) and in central and peripheral nervous system regulation have been implicated.

Treatments for overactive bladder syndrome include conservative interventions such as behavior modification and pelvic floor training, and pharmacologic treatments. More invasive options, such as surgery or neuromodulation, may be indicated when the symptoms are more severe or when conservative measures are unsatisfactory. The mechanism by which neuromodulation acts to improve symptoms is not well understood, but electrical stimulation of the afferent nerves may allow for appropriately transmitting bladder sensations.

Fecal incontinence can be categorized into urgent or passive cases. Causes are multiple: the most common symptom of fecal incontinence is diarrhea, but constipation can also occur. Multiple treatment options are available, with prescription medications being most frequently used as first-line therapy (National Institute for Diabetes and Digestive and Kidney Diseases, 2017).

Two devices are currently approved to provide sacral neuromodulation (U.S. Food and Drug Administration, 2022). These are the InterStim and Axonics r-SNM Systems. The U.S. Food and Drug Administration (1997)

authorized the use of the InterStim sacral neuromodulation device in 1997. The Administration approved the Axonics r-SNM System in 2019 (U.S. Food and Drug Administration, 2019).

The InterStim device lasts for about 4.4 years, after which it must be replaced. The implantation procedure requires two stages. The first consists of a "test" stimulation using a percutaneous needle to stimulate the S3 nerve root. If this results in a favorable response, then a pulse generator can be surgically implanted to provide long-term stimulation. The implantable pulse generator is usually placed in the fatty tissues overlying the buttocks, a shift from abdominal placement used in some earlier research. A permanent lead may be used for the test stimulation, which may be removed if the test is unsuccessful. If the test is successful, the lead can be attached to the permanent implantable pulse generator, ensuring that stimulation is provided in the exact location as during the test period.

The Axonics r-SNM System is a miniaturized, rechargeable sacral neuromodulation system designed to deliver therapy for at least 15 years. The device does not require two steps for implantation. The longer period of 15 years before which explantation is expected to be necessary offers the potential to increase efficacy and to reduce procedures and costs.

Fecal incontinence, which can be caused by numerous factors, can be treated with medications, biofeedback therapy, vaginal balloons, bulking agents, and surgery. In cases that are refractory to conservative treatments, sacral nerve stimulation can also be considered (National Institute of Diabetes and Digestive and Kidney Diseases, 2017).

Findings

The American Urological Association guideline, first published in 2012 and most recently updated by Gormley (2019), states that sacral neuromodulation may be offered as third-line treatment in a "carefully selected patient population characterized by severe refractory overactive bladder symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure." These recommendations are based upon strength of evidence of Grade C (see Appendix).

The International Consultation on Incontinence guideline includes support for sacral neuromodulation in both urinary and fecal incontinence as third-line treatment for refractory cases (Abrams, 2017).

Results of recent large reviews addressing efficacy and safety of sacral neuromodulation are summarized below:

Overactive bladder

A network meta-analysis of 21 studies (n = 1,433) documented that in adults with overactive bladder syndrome, sacral neuromodulation was more effective than other treatments for quality of life, urinary episodes, and urinary frequency, but not for urgency incontinence episodes or number of pads (Huang, 2023).

A meta-analysis of 45 randomized controlled trials of women by the European Association of Urology showed similar success rates and a superior success rate for sacral nerve stimulation compared with antimuscarines (61% versus 42%, *P* = .02). Sacral nerve stimulation had a similar efficacy rate compared with Onabotulinumtoxin-A. The removal and revision rates for stimulation were 9% and 3%, respectively (Farag, 2023).

A meta-analysis of 55 studies (n = 32,507) comparing treatments found sacral neuromodulation was most likely to be ranked first for reducing micturition frequency, urgency episodes, and urgency urinary incontinence episodes (Liu, 2022).

A comprehensive literature search concluded sacral neuromodulation was safe and effective in the short and long term. In studies with at least two years follow-up, surgical re-intervention was high (median 33.2%). The review suggested ways to optimize success (Tilborghs, 2022).

A systematic review of 14 articles of sacral electric stimulation used to treat children found consistently positive results (improved outcomes with few adverse effects). Limits are a dearth of long-term outcomes and heterogeneity in reporting, as there is no standard protocol for the pediatric population (Casal Beloy, 2021).

A review of 24 studies of men assessed treatment options other than antimuscarinics but found little data on nerve stimulation (De Nunzio, 2021).

A study of symptomatic persons (n = 590) found women undergo neuromodulation and experience initial success more frequently than men. Urge incontinence episodes improved only in men and urge incontinence severity improved only in women (Nguyen, 2018).

A systematic review of 99 studies found improvement after sacral neuromodulation was superior to antimuscarinic treatment (Olivera, 2016).

Urinary incontinence

A review of four recent studies showed sacral neuromodulation and onabotulinumtoxinA had similar success in reducing urinary incontinence over two years (Abreu-Mendes, 2021).

A systematic review/network meta-analysis of 17 articles in which subjects were followed for three to six months found sacral neuromodulation had the greatest reduction in urinary incontinence episodes and voiding frequency, compared with onabotulinumtoxinA and percutaneous tibial nerve stimulation (Lo, 2020).

A systematic review indicated that sacral nerve stimulation has been associated with a 50% to 80% improvement in urinary and bowel dysfunction. Greater efficacy was observed when using especially high frequency sacral neuromodulation, a narrow/wide pulse, and use of short cycling intervals (Assmann, 2020).

A systematic review and meta-analysis of nine studies (n = 1,649) found onabotulinumtoxinA and sacral neuromodulation reduced refractory urinary urge incontinence for six months after treatment. Sacral neuromodulation was inferior in treatment but superior in safety (Niu, 2018).

A systematic review of 30 studies included findings included data that sacral nerve stimulation provided benefits in refractory cases of urinary incontinence in women (Schreiner, 2013).

A systematic review of 73 studies observed similar reductions in incontinence episodes and voiding frequency for implanted sacral nerve stimulation and percutaneous posterior tibial nerve stimulation (Monga, 2012).

Fecal incontinence

A review of 13 studies found that sacral neuromodulation after low anterior resection significantly improved symptoms and quality of life (Ram, 2020).

A systematic review/meta-analysis found that sacral nerve stimulation after low anterior resection reduced fecal incontinence by an average of 67% (Huang, 2019).

A systematic review showed sacral nerve stimulation in children showed varying degrees of effectiveness in improving bowel movements per day, transit times, and soiling (Dewberry, 2019).

A review of 14 papers revealed that sacral neuromodulation reduced constipation in children by 79% to 86% but had a complication rate of 17% to 50% (Iacona, 2019).

A systematic review/meta-analysis of four studies (n = 302) indicated sacral neuromodulation had similar effectiveness and greater improvements in functional outcomes and quality of life compared with percutaneous tibial nerve stimulation (Simillis, 2018).

A systematic review calculated a cure rate of 38.6% for fecal incontinence after treatment with sacral neuromodulation (Riemsma, 2017).

A Cochrane review of eight studies found sacral nerve stimulation improved incontinence, but did not improve constipation symptoms (Thaha, 2015).

Other

A systematic review of 11 studies (n = 291) of persons with neurogenic bladder revealed sacral neuromodulation was associated with a variety of improvements, including: incontinence episodes, frequency per 24 hours, voiding volume, cystometric capacity, post-void residual volume, and clean intermittent self-catheterization per 24 hours, each significant at $P < .001$ (Wei, 2023).

A systematic review of 21 publications showed that persons with urinary tract dysfunction found sacral neuromodulation improved leakage episodes ≥ 50% (range 29% to 76%). The overall dry rate ranged between 43% and 56%. Overall improvement after percutaneous tibial neural stimulation ranged from 54% to 59% (Tutolo, 2018).

An analysis (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 neuromodulation. The overall cost of onabotulinumtoxinA treatment was lower than that of sacral neuromodulation treatment ($2,896 versus $3,454 at one year, $15,343 versus $16,189 at three years, each $P < .01$) (Chughtai, 2020).

References

On November 28, 2023, 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 “Interstim,” “sacral neuromodulation,” and “sacral nerve stimulation,” ”overactive bladder,” “urinary incontinence,” and “stress 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.

Appendix

The American Urological Association/Society of Urodynamics and Female Pelvic Medicine and Urogenital Reconstruction Guidelines: Diagnosis and treatment of non-neurogenic overactive bladder in adults (Gormley, 2019).

First-line treatment: behavioral therapies:

1. Clinicians should offer behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, and fluid management) as first-line therapy to all patients with overactive bladder. Standard (Evidence Strength Grade B).
2. Behavioral therapies may be combined with pharmacologic management. Recommendation (Evidence Strength Grade C).

Second-line treatments: pharmacologic management:

3. Clinicians should offer oral anti-muscarinics or oral β3-adrenoceptor agonists as second-line therapy. Standard (Evidence Strength Grade B).
4. If an immediate release and an extended release formulation are available, then extended release formulations should preferentially be prescribed over immediate release formulations because of lower rates of dry mouth. Standard (Evidence Strength Grade B).
5. Transdermal oxybutynin (patch or gel) may be offered. Recommendation (Evidence Strength Grade C).
6. If a patient experiences inadequate symptom control and/or unacceptable adverse drug events with one antimuscarinic medication, then a dose modification or a different anti-muscarinic medication or a β3-adrenoceptor agonist may be tried. Clinical Principle.
7. Clinicians may consider combination therapy with an anti-muscarinic and β3-adrenoceptor agonist for patients refractory to monotherapy with either anti-muscarinics or β3-adrenoceptor agonists. Option (Evidence Strength Grade B).
8. Clinicians should not use anti-muscarinics in patients with narrow-angle glaucoma unless approved by the treating ophthalmologist and should use anti-muscarinics with extreme caution in patients with impaired gastric emptying or a history of urinary retention. Clinical Principle.
9. Clinicians should manage constipation and dry mouth before abandoning effective anti-muscarinic therapy. Management may include bowel management, fluid management, dose modification or alternative antimuscarinics. Clinical Principle.
10. Clinicians must use caution in prescribing anti-muscarinics in patients who are using other medications with anticholinergic properties. Expert Opinion.
11. Clinicians should use caution in prescribing anti-muscarinics or β3-adrenoceptor agonists in the frail overactive bladder patient. Clinical Principle.
12. Patients who are refractory to behavioral and pharmacologic therapy should be evaluated by an appropriate specialist if they desire additional therapy. Expert Opinion.

Third-line treatments: peripheral tibial nerve stimulation and neuromodulation:

13. Clinicians may offer intradetrusor onabotulinumtoxinA (100U) as third-line treatment in the carefully-selected and thoroughly-counseled patient who has been refractory to first- and second-line overactive bladder treatments. The patient must be able and willing to return for frequent post-void residual evaluation and able and willing to perform self-catheterization if necessary. Standard (Evidence Strength Grade B).
14. Clinicians may offer peripheral tibial nerve stimulation as a third-line treatment in a carefully selected patient population. Recommendation (Evidence Strength Grade C).
15. Clinicians may offer sacral neuromodulation as a third-line treatment in a carefully selected patient population characterized by severe refractory overactive bladder symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure. Recommendation (Evidence Strength Grade C).
16. Practitioners and patients should persist with new treatments for an adequate trial in order to determine whether the therapy is efficacious and tolerable. Combination therapeutic approaches should be assembled methodically, with the addition of new therapies occurring only when the relative efficacy of

the preceding therapy is known. Therapies that do not demonstrate efficacy after an adequate trial should be ceased. Expert Opinion.

Fourth-line treatments: augmentation cystoplasty and urinary diversion

17. In rare cases, augmentation cystoplasty or urinary diversion for severe, refractory, complicated overactive bladder patients may be considered. Expert Opinion.

Additional treatments:

18. Indwelling catheters (including transurethral, suprapubic, etc.) are not recommended as a management strategy for overactive bladder because of the adverse risk/benefit balance except as a last resort in selected patients. Expert Opinion.

Follow-up:

19. The clinician should offer follow up with the patient to assess compliance, efficacy, side effects and possible alternative treatments. Expert Opinion