PROVIDER*ALERT*

AmeriHealth Caritas Louisiana

To: **AmeriHealth Caritas Louisiana Providers**

Date: **July 8, 2025**

Subject: **LDH Approved Clinical Policy – Sacral Nerve Modulation Stimulation**

Summary: Policy for Sacral Nerve Modulation Stimulation Guideline

AmeriHealth Caritas Louisiana would like to make you aware of a revised clinical policy that has been approved by the Louisiana Department of Health in accordance with La. R.S. 46:460.54. The guideline will be located at the following link on our website under Clinical Policies:
https://www.amerihealthcaritasla.com/provider/resources/index.aspx

Reminder: If your practice is not registered with our website portal-NaviNet, we highly recommend registering. To register, please visit www.navinet.net to sign up or contact your Provider Account Executive for details.

Questions: Thank you for your continued support and commitment to the care of our members. If you have questions about this communication, please contact AmeriHealth Caritas Louisiana Provider Services at 1-888-922-0007 or your Provider Network Management Account Executive.

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Sacral nerve modulation/stimulation

Clinical Policy ID: CCP.1522

Recent review date: ~~2/2024~~ **2/2025**

Next review date: ~~6/2025~~ **6/2026**

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

AmeriHealth Caritas Louisiana has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Louisiana's 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, on a case-by-case basis by AmeriHealth Caritas Louisiana 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 Louisiana's 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 Louisiana's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Louisiana will update its clinical policies as necessary. AmeriHealth Caritas Louisiana'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 members ages 18 and older with** severe, refractory overactive bladder syndrome, **nonobstructive urinary retention**, and urinary incontinence when **both** ~~all of the following~~ criteria are met ~~(Abrams, 2017; Gormley, 2019)~~ **(American Urological Association [Cameron, 2024; Ginsberg, 2021]; International Continence Society [Goldman, 2018]; National Institute for Health and Care Excellence, 2015):**

- ~~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~~ **are** ineffective, **not tolerated, refused**, or ~~are~~ 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 ~~or sacral neuromodulation~~ is clinically proven and, therefore, **may be** medically necessary **as a treatment for members ages 18 and older with fecal incontinence** ~~as a third-line treatment~~

~~option for fecal incontinence when the above criteria are met, plus all of the following~~ **(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.**
- ~~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~~. **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).

~~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).~~

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).**
- ~~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.~~

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

~~Overactive Bladder~~

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** ~~articles~~ of sacral ~~electric~~ **nerve** stimulation ~~used to treat children~~ 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).

~~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~~

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).

~~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).~~

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).

~~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).~~

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.

Abrams P, Cardozo L, Wagg A, Wein A (eds). Incontinence (6th Edition). 6th International Consultation on Incontinence, Tokyo, September 2016, pp. 1-2636. https://www.ics.org/publications/ici_6/Incontinence_6th_Edition_2017_eBook_v2.pdf. Published 2017.

~~Abreu-Mendes P, Martins-Silva C, Antunes-Lopes T, Cruz F. Treatment of non-neurogenic lower urinary tract symptoms – A review of key publications from 2018 onward. *Eur Urol Focus*. 2021;7(6):1438-1447. Doi: 10.1016/j.euf.2020.06.015.~~

Amundsen CL, Sutherland SE, Kielb SJ, Dmochowski RR. Sacral and implantable tibial neuromodulation for the management of overactive bladder: A systematic review and meta-analysis. *Adv Ther*. 2024; Doi: 10.1007/s12325-024-03019-0.

~~Assmann R, Douven P, Kleijnen J, et al. Stimulation parameters for sacral neuromodulation on lower urinary tract and bowel dysfunction-related clinical outcome: A systematic review. *Neuromodulation*. 2020;23(8):1082-1093. Doi: 10.0000/ner.13255.~~

Assmann SL, Keszthelyi D, Kleijnen J, et al. Guideline for the diagnosis and treatment of faecal incontinence-a UEG/ESCP/ESNM/ESPCG collaboration. *United European Gastroenterol J*. 2022;10(3):251-286. Doi: 10.1002/ueg2.12213.

Bordeianou LG, Thorsen AJ, Keller DS, et al. The American Society of Colon and Rectal Surgeons clinical practice guidelines for the management of fecal incontinence. *Dis Colon Rectum*. 2023;66:647-661. Doi: 10.1097/DCR.0000000000002776.

Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. *J Urol*. 2024;212(1):11-20. Doi: 10.1097/JU.0000000000003985.

Casal Beloy I, Garcia-Novoa MA, Gonzalez MG, Somoza Argibay I. Update on sacral neuromodulation and overactive bladder in pediatrics: A systematic review. *Arch Esp Urol*. 2021;74(7):699-708. Doi: 10.1016/j.purol.2021.06.011.

Chughtai B, Clemens JQ, Thomas D, et al. Real world performance of sacral neuromodulation and onabotulinumtoxinA for overactive bladder: Focus on safety and cost. *J Urol.* 2020;203(1):179-184. Doi: 10.1097/ju.0000000000000462.

~~De Nunzio C, Brucker B, Bschleipfer T, et al. Beyond antimuscarinics: A review of pharmacological and interventional options for overactive bladder management in men. *Eur Urol*. 2021;79(4):492-504. Doi: 10.1016/j.eururo.2020.12.032~~.

Dewberry L, Trecartin A, Pena A, St. Pierre M, Bischoff A. Systematic review: Sacral nerve stimulation in the treatment of constipation and fecal incontinence in children with emphasis in anorectal malformation. *Pediatr Surg Int*. 2019;35(9):1009-1012. Doi: 10.1007/s00383-019-04515-z.

Eggers E, Crouss T, Beausang J, et al. Long-term outcomes of sacral nerve stimulation on the treatment of fecal incontinence: A systematic review. *Neuromodulation*. 2024; Doi: 10.1016/j.neurom.2024.06.504.

Ginsberg DA, Boone TB, Cameron AP et al: The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Treatment and Follow-up. *J Urol* 2021;206(5):1106-1113. Doi: 10.1097/JU.0000000000002239.

Goldman HB, Lloyd JC, Noblett KL, et al. International Continence Society best practice statement for use of sacral neuromodulation. *Neurourol Urodyn*. 2018;37(5):1823-1848. Doi: 10.1002/nau.23515.

Grimes WR, Stratton M. Pelvic floor dysfunction. [Updated 2023 Jun 26]. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. https://www.ncbi.nlm.nih.gov/books/NBK559246/. Published January 2025.

~~Gormley EA, Lightner DJ, Burgio KL et al: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline. *J Urol* 2012; 188: 2455. Unabridged version of this guideline. American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Guidelines. https://www.auanet.org/guidelines-and-quality/guidelines/overactive-bladder-(oab)-guideline. Published 2012. Amended 2014, 2019.~~

~~Haylen BT, de Ridder D, Freeman RM, et al. An international urogynecological association (IGUA)/international continence society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Int Urogynecol J.* 2010;21(1):5-26. Doi: 10.1007/s00192-009-0976-9.~~

Ho FCS, He C, Yao HH, O'Connell HE, Gani J. Efficacy of sacral neuromodulation and percutaneous tibial nerve stimulation in the treatment of chronic nonobstructive urinary retention: A systematic review. *Neurourol Urodyn*. 2021;40(5):1078-1088. Doi: 10.1002/nau.24694.

Huang Y, Koh H. Sacral nerve stimulation for bowel dysfunction following low anterior resection: A systematic review and meta-analysis. *Colorectal Dis*. 2019;21(11):1240-1248. Doi: 10.1111/codi.14690.

Huang J, Fan Y, Zhao K, et al. Comparative efficacy of neuromodulation technologies for overactive bladder in adults: A network meta-analysis of randomized controlled trials. *Neuromodulation*. 2023;26(8):1535-1548. Doi: 10.1016/j.neurom.2022.06.004.

Iacona R, Ramage L, Malakounides G. Current state of neuromodulation for constipation and fecal incontinence in children: A systematic review. *Eur J Pediatr Surg*. 2019;29(6):495-503. Doi: 10.1055/s-0038-1677485.

Kobashi KC, Vasavada S, Bloschichak A, et al. Updates to surgical treatment of female stress urinary incontinence (SUI): AUA/SUFU guideline (2023). *J Urol*. 2023;209(6):1091-1098. Doi: 10.1097/JU.0000000000003435.

Malallah M, Cameron A, Sack B. The evidence for implantable sacral neuromodulation in pediatric voiding dysfunction. *Curr Bladder Dysfunct Rep.* 2024;19:231–237. Doi: 10.1007/s11884-024-00759-1.

~~Liu P, Li Y, Shi B, Zhang Q, Guo H. Comparison of different types of therapy for overactive bladder: A systematic review and network meta-analysis. *Front Med (Lausanne)*. 2022;9:1014291. Doi: 10.3389//fmed/2022.1014291.~~

~~Lo CW, Wu M-Y, Yang S S-D, Jaw F-S, Chang S-J. Comparing the efficacy of OnabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis. *Toxins (Basel)*. 2020;12(2):128. Doi: 10.3390/toxins12020128.~~

Monga AK, Tracey MR, Subbaroyan J. A systematic review of clinical studies of electrical stimulation for treatment of lower urinary tract dysfunction. *Int Urogynecol J*. 2012;23(8):993-1005. Doi: 10.1007/s00192-012-1691-5.

National Institute for Health and Care Excellence. Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention. Interventional procedures guidance. Reference number:IPG536. https://www.nice.org.uk/guidance/ipg536. Published November 2015.

Radmayr C, Bogaert G, Bujons A, et al. for the European Association of Urology and the European Society for Paediatric Urology. EAU guidelines on paediatric urology. https://d56bochluxqnz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Paediatric-Urology-2024.pdf. Published 2024.

Nguyen LN, Bartley J, Killinger KA, et al. Does sex matter? A matched pairs analysis of neuromodulation outcomes in women and men. *Int Urol Nephrol*. 2018;50(5):825-832. Doi: 10.1007/s11255/-018-1843-8.

Niu H-L, Ma Y-H, Zhang C-J. Comparison of OnabotulinumtoxinA versus sacral neuromodulation for refractory urinary urge incontinence: A systematic review and meta-analysis of randomized controlled trials. *Int J Surg*. 2018;60:141-148. Doi: 10.1016/j.ijsu.2018.10.041.

Olivera CK, Meriwether K, El-Nashar S, et al. Nonantinuscarinic treatment for overactive bladder: A systematic review. *Am J Obstet Gynecol*. 2016;215(1):34-57. Doi: 10.1016/j.ajog.2016.01.156.

Ram E, Meyer R, Carter D, Gutman M, Rosin D, Horesh N. The efficacy of sacral neuromodulation in the treatment of low anterior resection syndrome: A systematic review and meta-analysis. *Tech Coloproctol*. 2020;24(8):803-815. Doi: 10.1007/s10151-020-02231-8.

Riemsma R, Hagen S, Kirschner-Hermanns R, et al. Can incontinence be cured? A systematic review of cure rates. *BMC Med*. 2017;15(1):63. Doi: 10.1186/s12916-017-0828.

Schreiner L, dos Santos TG, de Souza ABA, Nygaard CC, da Silva Filbo IG. Electrical stimulation for urinary incontinence in women: A systematic review. *Int Braz J Urol*. 2013;39(4):454-464. Doi: 10.1590/S1677-5538.IBJU.2013.04.02.

Simillis C, Lal N, Qiu S, et al. Sacral nerve stimulation versus percutaneous tibial nerve stimulation for faecal incontinence: A systematic review and meta-analysis. *Int J Colorectal Dis*. 2018;33(5):645-648. Doi: 10.1007/s00384-018-2976-z.

Thaha MA, Abukar AA, Thin NN, Ramsanahie A, Knowles CH. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane Database Syst Rev*, 2015;2015(8):CD004464. Doi: 10.1002/14651858.CD004464.pub3.

Trinidad S, Jensen A, Holder M, et al. Sacral nerve stimulation in children with medically refractory fecal incontinence or severe constipation. *J Pediatr Surg*. 2023;58(8):1594-1599. Doi: 10.1016/j.jpedsurg.2023.04.007.

Tilborghs S, DeWachter S. Sacral neuromodulation for the treatment of overactive bladder: Systematic review and future prospects. *Expert Rev Med Devices*. 2022;19(2):161-187. Doi: 10.1080/17434440.2022.2032655.

Tutolo M, Ammirati E, Heesakkers J, et al. Efficacy and safety of sacral and percutaneous tibial neuromodulation in non-neurogenic lower urinary tract dysfunction and chronic pelvic pain: A systematic review of the literature. *European Urol.* 2018;73(3):406-418. Doi: 10.1016/j.eururo.2017.11.002.

U.S. Food and Drug Administration. Axonics Sacral Neuromodulation System. Premarket approval — P190006. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190006. Decision date November 13, 2019.

U.S. Food and Drug Administration. InterStim. Premarket approval — P970004. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970004. Decision date September 29, 1997.

U.S. Food and Drug Administration. Premarket approval database searched using product code "EZW." https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. Page last updated January 6, 2025.

U.S. Food and Drug Administration. Virtis Sacral Neuromodulation System. Premarket approval — P170001. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170001A.pdf. Decision date January 11, 2023.

Wei Z, Zhang Y, Hou J, et al. Effectiveness and safety of sacral neuromodulation for neurogenic bladder. *Neurol Res*. 2023;45(6):520-529. Doi: 10.1080/01616412.2022.2162223.

Yang G, Xu Y, Qu G, Zhang Y. Refractory overactive bladder patients who chose sacral neuromodulation therapy after failed onabotulinumtoxin A treatment: A systematic review and meta-analysis. *PloS one*. 2020;15(3):e0230355. Doi: 10.1371/journal.pone.0230355.

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.

~~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