Medical Coverage Policy

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Sacral Nerve Stimulation for Urinary Voiding Dysfunction, Fecal Incontinence and Constipation

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s).

Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses sacral nerve stimulation (SNS) and implantable tibial nerve stimulation as a treatment for the involuntary leakage of urine or stool and constipation.

Coverage Policy

Urinary Voiding Dysfunction

Permanent sacral nerve stimulation (SNS) implantation for the treatment of urinary voiding dysfunction (i.e., urinary urge incontinence, nonobstructive urinary retention, overactive bladder symptoms, including urinary frequency and/or urgency, with or without incontinence) is considered medically necessary when there has been a beneficial clinical response to a screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms (e.g., urinary urgency, frequency, nocturia, incontinence).

Fecal Incontinence

Permanent SNS implantation for fecal incontinence is considered medically necessary when there has been a beneficial clinical response to a screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms.

SNS for the treatment of any other indication, including constipation is considered not medically necessary.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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

HCPCS Codes	Description
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)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

General Background

Sacral nerve stimulation (SNS), also known as sacral nerve neuromodulation (SNM), has been proposed as a treatment for urinary voiding dysfunction and fecal incontinence when there is a failure, intolerance, or contraindication to conservative medical management. While the exact mechanism of action is unclear, electrical stimulation may modulate aberrant signals between the sacral nerve roots and the central nervous system, decreasing bladder activity, and improving fecal continence in select patients. SNS is delivered using a programmable, surgically implanted neurostimulator device. Prior to receiving a permanent neurostimulator device, a screening trial of SNS is required. This trial may be accomplished using an external SNS stimulator during an outpatient percutaneous nerve evaluation (PNE) or a two-stage implant procedure. If there is a beneficial clinical response to a screening trial of SNS, as evidenced by at least a 50% improvement in reported symptoms, patients may receive permanent SNS implantation (Dmochowski, et al., 2025; Feldman, et al., 2020).

Urinary Voiding Dysfunction

Urinary voiding dysfunction includes urinary urge incontinence, nonobstructive urinary retention, and overactive bladder (OAB) symptoms, including urinary frequency and/or urgency, with or without incontinence. Urinary urge incontinence is the involuntary release of urine associated with urgency. Nonobstructive urinary retention refers to the inability to completely empty the bladder

in the absence of a physical blockage. OAB may cause urinary frequency, nocturia, or urgency. Urinary frequency includes complaints of needing to void often when it is bothersome or disruptive to daily life. Nocturia is the interruption of sleep one or more times to void. Urinary urgency makes postponing urination difficult. OAB may lead to incontinence. The management of urinary voiding dysfunction may take a stepwise approach and depends on the underlying cause, severity, and patient-specific factors. Treatments proposed for urinary voiding dysfunction include behavioral modifications, lifestyle changes, pelvic floor muscle training, biofeedback, bladder training, pharmacologic therapy, and neuromodulation. Treatments proposed for nonobstructive urinary retention include catheterization, pharmacologic therapy, behavioral management, neuromodulation, and surgery (Dmochowski, et al., 2025; American Urological Association, 2016).

U.S. Food and Drug Administration (FDA)

Devices that use SNS to treat urinary voiding dysfunction include the InterStim™ system (Medtronic Neuromodulation) and the Axonics® Sacral Neuromodulation System (Boston Scientific Corporation). The FDA classifies these systems as implanted electrical urinary continence devices (Product Code: EZW).

On September 29, 1997, the InterStim Therapy System For Urinary Control (Medtronic Neuromodulation) received FDA Premarket Approval (PMA) (P970004). The FDA Approval Order Statement notes, "This device is indicated for the treatment of urinary urge incontinence in patient [sic] who have failed or could not tolerate more conservative treatments." Supplements to the original PMA include approvals for the InterStim II, InterStim X system, and InterStim Micro system. According to the manufacturer, "Sacral neuromodulation delivered by the InterStim™ system for urinary control is indicated for the treatment of urinary retention and the symptoms of overactive bladder. Symptoms include urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination. It is for patients who have failed or could not tolerate more conservative treatments."

On November 13, 2019, the Axonics Sacral Neuromodulation System (Boston Scientific Corporation) received FDA PMA (P180046). The FDA Approval Order Statement notes, "The device is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments." Supplements to the original PMA include approvals for the Axonics F15 and Axonics R20. According to the manufacturer, "The Axonics R15 System for urinary control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence (leakage) and significant symptoms of urgency-frequency, either alone or in combination, in patients who have failed or could not tolerate more conservative treatments." Additionally, "The Axonics R20 System for urinary control is indicated for the treatment of the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments."

Literature Review - Urinary Voiding Dysfunction

Several randomized clinical trials (RCTs), prospective case series, retrospective analyses, and systematic reviews have demonstrated the safety and effectiveness of SNS for the treatment of urinary voiding dysfunction in select patients when there is failure, intolerance or contraindication to conservative medical management (Szymański, et al., 2019; Tutolo, et al., 2018; Siegel, et al., 2015; Noblett, et al., 2014; Herbison, et al., 2009; White, et al., 2008; van Kerrebroeck, et al., 2007, Sutherland, et al., 2007).

Fecal Incontinence

Fecal Incontinence is the involuntary leakage of fecal matter through the anus or inability to control the discharge of bowel contents. Severity ranges from the occasional unintentional loss of flatus to seepage of liquid fecal matter or complete evacuation of bowel contents. The management of fecal incontinence may take a stepwise approach and depends on the underlying cause, severity, and patient-specific factors. Treatments proposed for fecal incontinence include supportive measures, pharmacologic therapy, biofeedback, plugs, sphincter bulking agents, SNS, radiofrequency therapy, and surgery (Feldman, et al., 2020).

U.S. Food and Drug Administration (FDA)

Devices that use SNS to treat fecal incontinence include the Medtronic Interstim™ Sacral Nerve Stimulation Therapy System (Medtronic Neuromodulation) and the Axonics Sacral Neuromodulation System (Boston Scientific Corporation). The FDA classifies these systems as implanted electrical devices intended for the treatment of fecal incontinence (Product Code: QON).

On March 14, 2011, the Medtronic Interstim Sacral Nerve Stimulation Therapy System (Medtronic Neuromodulation) received FDA PMA (P080025). The FDA Approval Order Statement notes, "The device is indicated for the treatment of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments." Supplements to the original PMA include approvals for the InterStim II, InterStim X system, and InterStim Micro system. According to the manufacturer, "Sacral neuromodulation delivered by the InterStim™ system for bowel control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments."

On September 30, 2019, the Axonics Sacral Neuromodulation System (Boston Scientific Corporation) received FDA PMA (P190006). The FDA Approval Order Statement notes, "This device is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments." Supplements to the original PMA include approvals for the Axonics F15 and Axonics R20. According to the manufacturer, "Axonics SNM Therapy for bowel control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments."

Literature Review - Fecal Incontinence

High-quality RCT data is limited regarding the safety and efficacy of SNS for fecal incontinence following a successful screening trial (Tjandra, et al., 2008; Leroi, et al., 2005). However, there is a sufficient body of evidence to support the use of SNS for this indication, including prospective and retrospective studies, systematic reviews, and meta-analyses (Eggers, et al., 2024; Rydningen, et al., 2017; Hull, et al., 2013; Damon, et al., 2013; Devroede, 2012; Boyle, et al., 2011; Mellgren, 2011; Tan, et al. 2011; Uludag, et al., 2011; Michelson, et al., 2010; Wexner, et al., 2010; Matzel, et al., 2009; Meurette, et al., 2009; Chan, 2008; Mowatt, et al., 2008; Shamliyan, et al., 2007; Leroi, et al., 2005). These studies demonstrate an acceptable safety profile for SNS, decreased frequency of fecal incontinence, and increased QOL.

Other Indications

Less commonly, SNS has been proposed for the treatment of various other conditions, including constipation and pelvic pain. Constipation describes altered bowel movements that include hard stools, difficulty with defecation, and a sensation of incomplete evacuation. Chronic constipation may be diagnosed when the symptoms of constipation last for three consecutive months, with the onset of symptoms occurring 6 months prior to diagnosis. The management of constipation may

take a stepwise approach and depends on the underlying cause, severity, and patient-specific factors. Treatments proposed for constipation include lifestyle changes, psychological support, dietary changes and fiber supplementation, pharmacologic therapy, defecation training, anorectal biofeedback, SNS, and surgery (Feldman, et al., 2020). The treatment for pelvic pain varies, depending on the cause and severity, but may include lifestyle changes, psychological support, pelvic floor physical therapy, and pharmacologic therapy (Dmochowski, et al., 2025).

Literature Review - Other Indications

It remains unclear which patients are most likely to benefit from SNS for the treatment of constipation and the magnitude of any benefit (Feldman, et al., 2020). Data is limited and there is insufficient evidence in the peer-reviewed scientific literature to support the safety and effectiveness of SNS for the treatment of constipation (Emile, et al., 2025; Maeda, et al., 2017; Zerbib, et al., 2017; Pilkington, et al., 2017; Thaha, et al. 2015). However, it may be reasonable to offer SNS to patients with chronic pelvic pain syndrome when accompanied by urinary frequency and urgency (Dmochowski, et al., 2025.) Of note, there are no SNS devices approved by the FDA for the treatment of constipation or pelvic pain.

Emile et al. (2025) conducted a systematic review and meta-analysis to assess the outcome of SNM in adult patients with chronic constipation. The systematic review included five RCTs and 187 individuals (93.6% female) (median age of 42.5 years). Of the total, 154 individuals underwent SNM, including 86 individuals who were crossed over to sham stimulation. Thirty-three individuals only received conservative treatment, creating a control group of 119 individuals. The primary outcome was improvement in constipation and QOL. The secondary outcome was adverse events after treatment. The median follow-up was 6 (range: 4.5 to 19) months. The study results revealed that the relief of constipation odds after SNM were similar to those in the control group using a random-effect model (odds ratio [OR]: 1.92, 95% Confidence Interval [CI]: 0.68 to 5.42, p=0.217). The median percentage of reduction in the Cleveland Clinic Florida/Wexner Constipation Score was 27.9% in the SNM group versus 18.4% in the control group. There were no significant QOL differences observed. Both groups had similar odds of adverse events odds (OR: 2.22, 95% CI: 0.19 to 25.53, p = 0.521). The authors concluded that SNM was a relatively safe treatment, but that it was not associated with any tangible improvements in constipation or QOL. Limitations of this systematic review and meta-analysis include the small number of studies and patients assessed, low certainty of evidence regarding outcomes, methodologic heterogeneity, and short-term follow-up.

A Cochrane review of randomized or quasi-randomized trials (n=8 studies) by Thaha et al. (2015) assessed the effectiveness of SNS using implanted electrodes for the treatment of fecal incontinence and constipation in adults. Of the eight trials, two crossover studies (n=61 patients) assessed SNS for constipation. Patients in both studies underwent permanent SNS implantation following a three-week trial of temporary stimulation. Outcomes measured in the studies included frequency of stools and constipation symptoms, as well as QOL. In the larger trial (Dinning, et al. 2015) (n=59 patients), SNS did not improve frequency of bowel movements. Seventy-three adverse events were reported, including pain at site of the implanted pulse generator (n=32), wound infection (n=12), and urological events (n=17). The authors found limited evidence to suggest that SNS can improve fecal incontinence in a subset of patients. However, SNS was not found to improve symptoms in patients with constipation. Study results are limited by the number of studies and small sample sizes.

Professional Societies/Organizations

American College of Gastroenterology (ACG): ACG published a guideline regarding the management of benign anorectal disorders that states, "We recommend SNS for patients with

moderate to severe FI [fecal incontinence] who have failed conservative measures, biofeedback, and other low-cost, low-risk techniques (strong recommendation; quality of evidence: low)." The ACG also notes that, "Three RCTs have shown no benefit of SNS in constipation (regardless of type). In addition, the long-term complication rate is considerable, with 61% reporting device-related adverse events in a long-term (60 months) follow-up study. Therefore, this procedure cannot be recommended in patients with constipation of any type" (Wald, et al., 2021).

American College of Obstetricians and Gynecologists (ACOG): ACOG published a practice bulletin on fecal incontinence that states SNS can be considered as a surgical treatment option for women with fecal incontinence with or without anal sphincter disruption who have failed conservative treatment. ACOG also states that surgical treatment options should be reserved for those who have failed conservative measures (with the exception of fistulas or rectal prolapse) because these treatments provide short-term improvement and are associated with more frequent and more severe complications compared to nonsurgical treatments (ACOG, 2019; Reaffirmed 2023).

American College of Obstetricians and Gynecologists (ACOG)/American Urogynecologic Society (AUGS): ACOG/AUGS published a practice bulletin for urinary incontinence in women that states sacral neuromodulation can be considered for patients with refractory urinary urge incontinence who have failed conservative treatment, including bladder training, pelvic floor physical therapy with biofeedback, and pharmacologic treatment (ACOG/AUGS, 2015; Reaffirmed, 2025).

American Society of Colon and Rectal Surgeons (ASCRS): ASCRS published a clinical practice guideline for the management of fecal incontinence that states, "Sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with or without sphincter defects." (Grade of Recommendation: Conditional based on low quality evidence.) (Bordeianou, et al., 2023)

American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU): AUA/SUFU (Cameron, et al., 2024) published a guideline regarding the diagnosis and treatment of idiopathic OAB that states:

"Guideline Statement 23"

- "Clinicians may offer minimally invasive procedures to patients who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies. (Clinical Principle)"

- "Minimally invasive treatment options for OAB including PTNS [percutaneous tibial nerve stimulation], implantable tibial nerve stimulation, BTX, and SNM have all been associated with high success rates, durable efficacy, and excellent patient satisfaction; however, the patient populations that have been studied are largely patients who have not had an adequate response to behavioral measures and medication management."

- "These interventions would offer considerable therapeutic benefits for naïve patients who do not want to or cannot pursue behavioral or pharmacological treatment options. There is a paucity of data in treatment naïve patients utilizing minimally invasive interventions. The lack of these studies should not preclude the practitioner from offering these interventions in the properly selected and counselled patient. Such studies however are needed."

"Guideline Statement 25"

- "In patients with OAB who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy, clinicians should offer sacral neuromodulation, percutaneous tibial nerve stimulation, and/or intradetrusor botulinum toxin injection. (Moderate Recommendation; Evidence Level: Grade A)"

- Clinicians may consider SNM as a therapy option for patients who have not achieved satisfactory outcomes with other OAB therapies. SNM has shown effectiveness in patients refractory to behavioral therapy and pharmacotherapy. High quality data evaluating the impact of SNM settings are lacking; however, a secondary analysis of a large RCT found that maximal intraoperative responses in the more distal electrodes predicts better SNM outcome. Adverse events reported with SNM include surgical revision for pain or infection, device discomfort, and lead migration."

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Syan et al. (2020) conducted a study that analyzed if racial and socioeconomic factors influenced the utilization of advanced therapies in commercially insured patients with overactive bladder. Through a query of Optum, a national claims database, the study results revealed that Asian and Hispanic individuals were least likely to utilize sacral nerve stimulation therapy and most likely to use percutaneous tibial nerve stimulation compared to Black and White individuals. Female gender, younger age (< 65), higher annual income ≥ $40K, and prior use of oral medications were significantly associated with receiving advanced therapies. In addition, non-white race, lower education level (less than a bachelor's degree), and Northeast region were associated with a lower likelihood of receiving advanced therapies ($p<0.05$ for all).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Sacral Nerve Stimulation For Urinary Incontinence (230.18)	1/1/2002
LCD	Palmetto	Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence (L39543)	11/5/2023

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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Revision Details

Type of Revision	Summary of Changes	Date
Focused Review	• Removed policy statement for screening trial of sacral nerve stimulation (SNS) for Urinary Voiding Dysfunction. • Removed policy statement for screening trial of sacral nerve stimulation for Fecal Incontinence.	11/15/25
Annual review	• Removed policy statement for Implantable Tibial Nerve Stimulation. • Title change	10/15/2025
Annual review	• Removed policy statement for:	10/15/2024

Type of Revision	Summary of Changes	Date
	○ Replacement/revision of a sacral nerve stimulator ○ Percutaneous tibial nerve stimulation • Revised policy statement for sacral nerve stimulation for any other indication	
Annual review	• Updated to new template and formatting standards. • Removed policy statement for PTNS maintenance therapy and number of treatments allowed. • Removed EIU policy statement for PTNS for fecal incontinence and constipation.	10/15/2023