

MEDICAL POLICY

POLICY TITLE	SACRAL NERVE NEUROMODULATION-STIMULATION
POLICY NUMBER	MP 1.033

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input checked="" type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	5/1/2026

POLICY

Urinary Incontinence and Non-obstructive Retention

Criteria A

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in individuals who meet all the following criteria:

1. There is a diagnosis of at least one of the following:
 - o Urge incontinence
 - o Urgency-frequency syndrome
 - o Non-obstructive urinary retention
 - o Overactive bladder
2. There is documented failure or intolerance to at least two conventional conservative therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy).
 - o The member is an appropriate surgical candidate.
 - o Incontinence is not related to a neurologic condition.

Criteria B

Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in individuals who meet all the following criteria:

1. All of criteria in A.1 and 2 above are met.
2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Other urinary/voiding applications of sacral nerve neuromodulation are considered **investigational**, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or other types of chronic voiding dysfunction). There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Fecal Incontinence

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Criteria A

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in individuals who meet all the following criteria:

1. There is a diagnosis of chronic fecal incontinence of greater than two (2) incontinent episodes on average per week for more than six (6) months or for more than 12 months after vaginal childbirth.
2. There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy.
3. The individual is an appropriate surgical candidate.
4. The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease.
5. Incontinence is not related to a neurologic condition.
6. The member has not had rectal surgery in the previous 12 months or, in the case of cancer, the individual has not had rectal surgery in the past 24 months.

Criteria B

Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in individuals who meet all the following criteria:

- All of criteria in A. 1 through 6 above are met.
- A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Sacral nerve neuromodulation is **investigational** in the treatment of chronic constipation or chronic pelvic pain. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

The International Continence Society has defined overactive bladder syndrome (OAB) as “urinary urgency, usually accompanied by increased daytime frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry), in the absence of urinary tract infection or other detectable disease” (available at <https://www.ics.org/glossary/symptom/overactivebladderoaburgencysyndrome>).

Cross-References:

MP 1.134 Percutaneous and Implantable Tibial Nerve Stimulation

MP 2.398 Biofeedback as a Treatment of Fecal Incontinence or Constipation

MP 6.024 Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

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PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

DESCRIPTION/BACKGROUND

Treatment

Treatment using sacral nerve neuromodulation, also known as indirect sacral nerve stimulation, is one of several alternative modalities for patients with urinary or fecal incontinence (urge incontinence, significant symptoms of urgency-frequency, nonobstructive urinary retention) who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

The sacral nerve neuromodulation device consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet, kept by the patient, is used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for 4 to 7 days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device.

The second type of testing is a 2-stage surgical procedure. In the first stage, a quadripolar-tined lead is implanted (stage 1). The testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, they can proceed to stage 2 of the surgery, which is permanent implantation of the neuromodulation device. The 2-stage surgical procedure has been used in various ways. They include its use instead of PNE, for patients who failed PNE, for patients with an inconclusive PNE, or for patients who had a successful PNE to refine patient selection further.

The permanent device is implanted with the patient under general anesthesia. The electrical leads are placed in contact with the sacral nerve root(s) via an incision in the lower back, and the wire leads are extended through a second incision underneath the skin, across the flank to

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the lower abdomen. Finally, a third incision is made in the lower abdomen where the pulse generator is inserted and connected to the wire leads. Following implantation, the physician programs the pulse generator to the optimal settings for that patient. The patient can switch the pulse generator on and off by placing the control magnet over the area of the pulse generator for 1 to 2 seconds.

This evidence review does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Pelvic floor stimulation is addressed separately (see MP 6.024). Also, this review does not address devices that provide direct sacral nerve stimulation in individuals with spinal cord injuries.

Regulatory Status

In 1997, the InterStim® Sacral Nerve Stimulation system (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. In 1999, the device received FDA approval for the additional indications of urgency-frequency and urinary retention in patients without mechanical obstruction. In 2006, the InterStim II® System (Medtronic) was approved by FDA through the premarket approval process for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original and is reported to be suited for those with lower energy requirements or small stature. The device also includes updated software and programming options.

In 2011, the InterStim® System was approved by FDA through the premarket approval process for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.

The InterStim® device has not been specifically approved by FDA for treatment of chronic pelvic pain.

In 2020, the InterStim X™ device was approved by the FDA. This latest generation of the InterStim device does not require recharging and has a battery life of at least 10 years and up to 15 years if used at a low-energy setting.

The InterStim device has not been specifically approved by the FDA for the treatment of chronic pelvic pain.

In 2019, the Axonics® Sacral Neuromodulation System (Axonics) received premarket approval from the FDA for both fecal incontinence and treatment of urinary retention and symptoms of overactive bladder. This system has a rechargeable battery that has a device life of 15 years after implantation.

In 2023, the Virtis™ Sacral Neuromodulation System (Nuvectra) was approved by the FDA for treatment of urinary retention and symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency in patients who have failed more conservative treatments.

FDA product code: EZW.

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RATIONALE

Summary of Evidence

For individuals with urinary incontinence who have failed conservative treatment who receive SNM, the evidence includes RCTs, systematic reviews, and case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Results from the RCTs and case series with long-term follow-up have suggested that SNM reduces symptoms of urge incontinence, urgency-frequency syndrome, nonobstructive urinary retention, and overactive bladder in selected patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with fecal incontinence who have failed conservative treatment who receive SNM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Although relatively small, the available trials had a low risk of bias and demonstrated improvements in incontinence relative to alternatives. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with constipation who have failed conservative treatment who receive SNM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The available trials have not consistently reported improvements in outcomes with SNM. Additional studies are needed to demonstrate the health benefits of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic pelvic pain who receive SNM, the evidence is limited to case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

DEFINITIONS

PUDENDAL refers to external female genitalia.

STRESS INCONTINENCE is the involuntary leaking of urine during activities that increase pressure inside the abdomen, such as coughing, sneezing, or jogging.

URGE INCONTINENCE is defined as leakage of urine when there is a strong urge to void.

URGENCY-FREQUENCY is an uncontrollable urge to urinate, resulting in very frequent, small volumes.

URINARY RETENTION is the inability to completely empty the bladder of urine.

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence

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from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
64561	64581	64585	64590	64595	95970	95971	95972	A4290
C1767	C1778	C1787	C1883	C1897	E0745	E1399	L8678	L8679
L8680	L8681	L8682	L8684	L8685	L8686	L8687	L8688	0786T
0787T	0788T	0789T						

ICD-10-CM Diagnosis Codes	Description
N32.81	Overactive bladder
N39.41	Urge incontinence
N39.46	Mixed incontinence
R15.9	Full incontinence of feces
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition
R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination

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POLICY HISTORY

MP 6.024	04/30/2020 Consensus Review. Description/Background, Rationale and Reference updated. Coding reviewed. No change to policy statement.
	04/15/2021 Consensus Review. No change to policy statement. References reviewed and updated. Coding reviewed.
	12/14/2022 Consensus Review. No change to policy statement. References, policy guidelines and rationale reviewed and updated. FEP statement updated. Coding reviewed.
	05/26/2023 Consensus Review. No change to policy statement. References and background updated. Coding reviewed.
	11/29/2023 Administrative Update. New Codes added effective 01/01/2024.
	03/25/2024 Consensus Review. No change in policy statement. References updated. Coding reviewed with no coding changes.
	06/17/2025 Minor Review. Title change; formerly Sacral Nerve Neuromodulation/Stimulation and Pelvic Floor Stimulation Devices. Removed Pelvic Floor Stimulation statements and accompanying code and placed into MP 6.024. Added L8678 to coding table. Formatting and verbiage changes to sacral nerve stimulation statements; no change to intent. Updated background, rationale, and references.
	01/22/2026 Consensus review. Cross references updated. No changes to coding.

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