MASSACHUSETTS

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Medical Policy

Sacral Nerve Neuromodulation/Stimulation

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Policy Number: 153

BCBSA Reference Number: 7.01.69 (For Plan internal use only)

Related Policies

- Biofeedback as a Treatment of Fecal Incontinence or Constipation, #308
- Biofeedback as a Treatment of Urinary Incontinence, #173
- Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, #470
- Percutaneous Tibial Nerve Stimulation, #583

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Urinary Incontinence and Nonobstructive 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** of the following criteria:

1. There is a diagnosis of at least 1 of the following:
    a. Urge incontinence
    b. Urgency-frequency syndrome
    c. Non-obstructive urinary retention
    d. Overactive bladder
2. There is documented failure or intolerance to at least 2 conventional conservative therapies (eg, 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).
    a. The individual is an appropriate surgical candidate.
    b. 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 of the following criteria:

1. All of the criteria in A (1-2) 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 **INVESTIGATIONAL** including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition, (eg, detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or other types of chronic voiding dysfunction).

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Fecal Incontinence

Criteria A

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

1. There is a diagnosis of chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 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 individual 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 **MEDICALLY NECESSARY** in individuals who meet all of the following criteria:

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

Sacral nerve neuromodulation is **INVESTIGATIONAL** in the treatment of chronic constipation or chronic pelvic pain.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS Codes

HCPCS codes:	Code Description
A4290	Sacral nerve stimulation test lead, each

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if <u>medical necessity criteria</u> are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
N32.81	Overactive bladder
N39.41	Urge incontinence
N39.46	Mixed incontinence
N39.491	Coital incontinence
N39.492	Postural (urinary) incontinence
N39.498	Other specified urinary incontinence
R15.9	Full incontinence of feces
R32	Unspecified urinary incontinence
R33.0	Drug induced retention of urine

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

Description

Treatment

Treatment using sacral nerve neuromodulation, also known as indirect sacral nerve stimulation, is 1 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 (eg, 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. 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 percutaneous nerve evaluation, for patients who failed percutaneous nerve evaluation, for patients with an inconclusive percutaneous nerve evaluation, or for patients who had a successful percutaneous nerve evaluation 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 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 policy # 470). Also, this review does not address devices that provide direct sacral nerve stimulation in patients with spinal cord injuries.

Summary

Description

Sacral nerve neuromodulation, also known as sacral nerve stimulation, involves the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This evidence review addresses the use of sacral nerve neuromodulation to treat urinary or fecal incontinence, fecal nonobstructive retention, and chronic pelvic pain in individuals with intact neural innervation of the bladder and/or rectum.

Summary of Evidence

For individuals with urinary incontinence who have failed conservative treatment who receive sacral nerve neuromodulation, the evidence includes randomized controlled trials (RCTs) 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 sacral nerve neuromodulation 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 an improvement in the net health outcome.

For individuals with fecal incontinence who have failed conservative treatment who receive sacral nerve neuromodulation, the evidence includes RCTs, systematic reviews, and observational studies including several with long-term follow-up. 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 in selected patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with constipation who have failed conservative treatment who receive sacral nerve neuromodulation, the evidence includes RCTs, systematic reviews, and case series including several with long-term follow-up. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The available trials have not consistently reported improvements in outcomes with sacral nerve neuromodulation. Additional studies are needed to demonstrate the health benefits of this technology. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic pelvic pain who receive sacral nerve neuromodulation, the evidence is limited to systematic reviews of case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
6/2025	Annual policy review. References updated. Policy statements unchanged.
6/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
6/2020	Annual policy review. Minor edits to the policy section; statements unchanged.
5/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2018	Clarified coding information.
2/2017	Annual policy review. New references added
10/2016	Clarified coding information.
1/2016	Clarified coding information.
12/2015	Annual policy review. In both B.2 medically necessary statements, period of trial stimulation changed to “at least 48 hours.” Clarified coding information. Effective 12/1/2015.
12/2014	Annual policy review. Added close parenthesis to statement A 2 in the fecal incontinence policy statement - 2. There is documented failure or intolerance to conventional conservative therapy (eg, dietary modification, the addition of bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy.

9/2014	Annual policy review. New medically necessary indications described. Clarified medically necessary statement on fecal incontinence (clarifying length of time after surgery trial stimulation can take place). Coding information clarified. Effective 9/1/2014.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
1/2014	Coding information clarified.
12/2013	Clarified coding information
10/2013	Annual policy review. Revised medically necessary criteria. Effective 10/1/2013. Removed CPT codes 64585, 64595 as these codes do not apply to this policy.
2/2013	Annual policy review. Changes to policy statement. Effective 2/4/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group – Urology, Obstetrics and Gynecology. No changes to policy statements.
1/2011	Annual policy review. Changes to policy statement.
6/2010	Reviewed - Medical Policy Group- Urology. No changes to policy statements.
1/1/2010	Medical Policy 153 effective 1/1/2010.
12/2009	Annual policy review. No changes to policy statement.
11/2007	Annual policy review. Changes to policy statement.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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