Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Sacral Nerve Stimulation for Urinary and Fecal Incontinence

Policy Number: PG0306
Last Review: 09/08/2021

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Sacral nerve stimulation (SNS), also referred to as sacral nerve neuromodulation (SNM), is the implantation of a permanent device that stimulates the sacral nerves and is a treatment for urinary voiding dysfunction and fecal incontinence in which electrical impulses are delivered to sacral nerve root fibers S2, S3, or S4 to modulate the neural pathways that influence the functioning of the bladder, bowel, urinary, and anal sphincters, and the pelvic floor muscles. SNS has been reported to improve bowel and bladder control when behavioral and pharmacological therapies have failed in the management of fecal incontinence, urge incontinence, non-obstructive urinary retention and urgency-frequency syndrome. A temporary test stimulation is initially completed to determine if an implantable stimulator would be effective and if so then a permanent implantation is performed.

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

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 treatments that are more conservative. 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 the 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 system 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 the 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 the FDA for treatment of chronic pelvic pain.

FDA granted premarket approval application (PMA) to Axonics Rechargeable Sacral Neuromodulation (r-SNM) System to treat fecal incontinence in September 2019. The indication for use reads: "This device is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments."

FDA granted premarket approval application (PMA) to Axonics Rechargeable Sacral Neuromodulation (r-SNM) System to treat urinary incontinence in November 2019. The indication for use reads: "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."

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Sacral Nerve Stimulation (SNS) for urinary and fecal incontinence does not require prior authorization.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Urinary Voiding Dysfunction:

Paramount covers a percutaneous nerve stimulation or a temporarily implanted lead screening trial of SNS as medically necessary for an individual with chronic urinary voiding dysfunction and failure of, contraindication to, or intolerance to conservative medical management (e.g. pelvic floor exercises, pharmacotherapies) for ALL of the following indications:

1. There is a diagnosis of at least one of the following:
    - urinary urge incontinence
    - non-obstructive urinary retention
    - urinary urgency/frequency syndrome
    - overactive bladder
2. There is documented failure or intolerance to at least two (2) conventional conservative therapies
    - 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.
3. The patient is an appropriate surgical candidate, with ability to tolerate general anesthesia
4. Incontinence is not related to a neurologic condition

Paramount covers permanent SNS implantation as medically necessary when BOTH of the following criteria are met:

1. The individual has met the above criteria for a percutaneous screening trial of SNS
2. The individual experienced a beneficial clinical response to a trial of temporary percutaneous SNS as evidenced by at least a 50% improvement in reported symptoms over a period of at least 48 hours
3. Willing and capable of operating the implantable pulse generator and recording stool diary data

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., neurogenic bladder, interstitial cystitis/bladder pain syndrome, detrusor hyperreflexia, multiple sclerosis, spinal cord injury, prostate hypertrophy, or other types of chronic voiding dysfunction) and therefore not covered.

Fecal Incontinence:

Paramount covers a percutaneous nerve stimulation or a temporarily implanted lead screening trial of SNS for fecal incontinence as medically necessary when ALL of the following criteria are met:

1. There is a diagnosis of chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than six (6) months or for more than twelve (12) months after vaginal childbirth.
    - As determined by ≥ 2 diagnostic modalities (e.g., anal manometry, anal ultrasonography, sigmoidoscopy anal electromyography)
2. There is documented failure of, contraindication to, or intolerance to conservative medical management for at least a sufficient duration to fully assess its efficacy.
    - Conservative medical management such as dietary modification, the addition of bulking and pharmacologic treatment.
    - Behavioral therapy (e.g., biofeedback pelvic floor physiotherapy, supervised bowel training)
3. The patient is an appropriate surgical candidate, with ability to tolerate general anesthesia
4. Sphincter surgery is either not indicated or is contraindicated
5. Absence of a significant 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 involving the anus
6. Fecal incontinence is not secondary to another neurological condition such as peripheral neuropathy or complete spinal cord injury
7. The patient has not had rectal surgery in the previous twelve (12) months, or in the case of cancer, the patient has not had rectal surgery in the past twenty-four (24) months

Paramount covers permanent SNS implantation for fecal incontinence as medically necessary when BOTH of the following criteria are met:

1. The individual has met the above criteria for a percutaneous screening trial of SNS
2. The individual experienced a beneficial clinical response to a trial of temporary percutaneous SNS as evidenced by at least a 50% improvement in reported symptoms over a period of at least forty-eight (48) hours
3. Willing and capable of operating the implantable pulse generator and recording stool diary data

Paramount does not cover SNS for the treatment of any other indication, as there is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes; therefore, it is experimental, investigational or unproven.

Sacral nerve neuromodulation is considered investigational for the treatment of chronic constipation or chronic pelvic pain.

<u>Definitions</u>

- Urinary voiding dysfunction is usually defined as the inability to control urination and are divided into different types:
    - Urinary urge incontinence: Is defined as the involuntary leakage of urine when there is a strong urge to void due to bladder spasms or contractions with enough force to override the sphincter muscles of the urethra.
    - Urinary urgency-frequency incontinence: Is defined as strong and abnormal urge to urinate, resulting in frequent urination without a loss of the feeling of the fullness of the bladder.
    - Non-obstructed urinary retention: Is usually caused by weak pelvic floor muscles or dysfunction in the neural pathway between the brain and bladder and results in the inability to completely empty the bladder of urine.
    - Overactive bladder (OAB, Urgency) Syndrome: Defined as urinary urgency, usually accompanied by increased daytime frequency and/or nocturia, with urgency urinary incontinence (OAB-wet) or without (OAB-dry), in the absence of urinary tract infection or other detectable disease.

Treatment options for urinary voiding disorders may include behavioral strategies, pharmacological interventions, electrical stimulation or reconstructive surgery.

- Fecal incontinence is the inability to control bowel movements leading to feces leaking from the rectum.

Fecal incontinence may be caused by several factors including muscle damage, such as that experienced by childbirth, or after rectal surgery, or from damage to the nerves that control the anal muscle or regulate rectal sensation. Additionally, it may be caused by a reduction in the elasticity of the rectum, which shortens the time between the sensation of the stool and the urgent need to have a bowel movement. Surgery or radiation injury can scar and stiffen the rectum. Inflammatory bowel disease can also make the rectum less elastic.

Treatment depends on the cause of the fecal incontinence and may include dietary changes, drug therapy, bowel training, sacral nerve stimulation or surgery.

CODING/BILLING INFORMATION:
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrodes array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e. cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without programming, first hour
95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (e.g. rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex, spinal cord, or peripheral (i.e. peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
HCPCS CODES	
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator, implantable, non-rechargeable
C1778	Lead, neurostimulator, implantable
C1897	Lead, neurostimulator, test kit (implantable)
E0745	Neuromuscular stimulator, electrical shock unit
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
L8683	Radiofrequency transmitter (external) for use with 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, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 07/18/2014

Date	Explanation & Changes
07/18/14	• Policy created after TAWG review of the most current clinical evidence and determination of coverage made
06/18/15	• Policy reviewed and updated to reflect most current clinical evidence per TAWG
08/20/15	• SNS for urinary and fecal incontinence no longer requires a prior authorization per TAWG determination
12/21/2020	• Medical policy placed on the new Paramount Medical Policy Format
09/08/2021	• Policy reviewed and updated to reflect most current clinical evidence • Coding update, add CPT/HCPCS codes 64585, 64595, 95970, 95971, 95972, E0745, L8679, L8681, L8683, L8689, L8695
02/20/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/29/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
03/07/2024	• Medical policy placed on the new Paramount Medical Policy Format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review