PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 7.01.69

Sacral Nerve Neuromodulation/Stimulation

BCBSA Ref. Policy:	7.01.69	
Effective Date:	Dec. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Nov. 11, 2024	8.03.01 Functional Neuromuscular Electrical Stimulation
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

The brain communicates with the body by sending electrical signals along nerves. When it comes time to go to the bathroom, the brain sends signals to specific nerves that travel through the lower back to the muscles that control the opening and closing of the bladder and bowel. Weak electrical signals may be used to address certain kinds of bowel and bladder problems that have not responded to other treatments. This procedure is known as sacral nerve neuromodulation. Another name for it is sacral nerve stimulation. This procedure involves implanting a small device under the skin in the lower back area. Small wires are also implanted so that the electric current activates the nerve important to either bladder or bowel function. This treatment usually is done in two steps. The first is a temporary placement to find out if sacral nerve stimulation works. The second is surgery to place the permanent implant. This policy describes when sacral nerve stimulation may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Note: This policy addresses the InterStim System (see **Regulatory Status** section).

Service	Medical Necessity
Urinary Incontinence and Non-obstructive Retention	

Sacral nerve neuromodulation	**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:**
	• There is a diagnosis of at least one of the following:
	  ○ Urge incontinence
	  ○ Urgency-frequency syndrome
	  ○ Nonobstructive urinary retention
	  ○ Overactive bladder (see **Definition of Terms**)
	AND
	• There is documented failure or intolerance to at least 2 of the following conventional conservative therapies:
	• Behavioral therapy (e.g., biofeedback)
	• Bladder training (e.g., prompted voiding)
	• Pelvic floor muscle exercise training
	• Pharmacologic treatment for at least a sufficient duration to fully assess its efficacy
	• Failure of prior surgical corrective therapy)
	AND
	• The individual is an appropriate surgical candidate
	AND
	• Incontinence is not related to a neurologic condition (e.g., spinal cord injury) or a progressive systemic neurologic condition (e.g., multiple sclerosis, diabetic neuropathy)

Permanent implantation, sacral nerve neuromodulation device	**Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in individuals who meet ALL of the following criteria:** • All of the criteria above are met **AND** • A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours
Fecal Incontinence	

Service	Medical Necessity
Sacral nerve neuromodulation	**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:** • There is a diagnosis of chronic fecal incontinence of more than 2 incontinent episodes on average per week for more than 6 months, or for more than 12 months after vaginal childbirth **AND** • 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 **AND** • The individual is an appropriate surgical candidate **AND** • 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 **AND** • Incontinence is not related to a neurologic condition (e.g., spinal cord injury) or a progressive, systemic neurologic condition (such as multiple sclerosis, or diabetic neuropathy) **AND** • The individual has not had rectal surgery in the previous 12 months, or in the case of rectal cancer, the individual has not had rectal surgery in the past 24 months
Permanent implantation, sacral nerve neuromodulation device	**Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in individuals who meet all of the following criteria:** • All of the criteria above are met **AND** • A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Service	Investigational
Other applications, urinary incontinence and nonobstructive retention	**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).**
Other applications, chronic constipation or chronic pelvic pain	**Sacral nerve neuromodulation is investigational in the treatment of chronic constipation or chronic pelvic pain.**

Documentation Requirements
The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition • History and physical examination documenting the severity of the condition • Conventional conservative therapies that have been tried and failed • Any history of rectal surgery • Any neurologic conditions or history of spinal cord injury • If request is for permanent placement, results of trial

Coding

Sacral nerve neuromodulation involves several steps that are identified by the following codes.

Code	Description
CPT	
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed (new code effective 1/1/2024)
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator (new code effective 1/1/2024)
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)

Code	Description
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode 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
HCPCS	
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
E0745	Stimulator electronic shock unit
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode each (Note: Reported with 1-unit for each contact point on the implanted lead)
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Related Information

Definition of Terms

Overactive bladder (OAB): The International Continence Society has defined overactive bladder syndrome as "urinary urgency, usually with increased daytime frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry) urgency urinary incontinence, in the absence of urinary tract infection or other detectable disease" (available online at **https://www.ics.org/glossary/symptom/overactivebladderoaburgencysyndrome** Accessed May 13, 2024).

Evidence Review

Description

Sacral nerve neuromodulation (SNM), also known as sacral nerve stimulation, involves the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This policy addresses the use of SNM 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.

Background

Treatment

Treatment using SNM, also known as indirect sacral nerve stimulation, is one of several alternative modalities for individuals 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 SNM 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 individual, 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, individuals 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 individual 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 four to seven days. This lead is connected to an external stimulator, which is carried by individuals in their pocket or on their belt. The results of this test phase are used to determine whether individuals are appropriate candidates for the permanent device. If individuals show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device.

The second type of testing is a two-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 individuals 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 individuals who failed PNE, for individuals with an inconclusive PNE, or for individuals who had a successful PNE to refine individual selection further.

The permanent device is implanted with the individual 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 individual. The individual can switch the pulse generator between on and off by placing the control magnet over the area of the pulse generator for one to two seconds.

Summary of Evidence

For individuals with urinary incontinence who have failed conservative treatment who receive SNM, the evidence includes randomized controlled trials (RCTs) and case series. The 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 individuals. 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, systematic reviews and observational studies including several with long-term follow-up. The 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 individuals. 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 SNM, the evidence includes RCTs, systematic reviews, and case series including several with long-term follow-up. The 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 that the technology results in an improvement in the net health outcome.

For individuals with chronic pelvic pain who receive SNM, the evidence is limited to systematic reviews of case series. The 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03811821	Comparative Effects of Biofeedback, Sacral Nerve Stimulation, and Injectable Bulking Agents for Treatment of Fecal Incontinence: The Fecal Incontinence Treatment Study (FIT) Study	271	Dec 2025
NCT04713085	Sacral Nerve Stimulation in Children and Adolescents With Chronic Constipation: a Case-control Study on Invasive and Non-invasive Neuromodulatory Treatment	30	Dec 2023

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04232696[a]	Clinical Study of Neuaspera's Implantable Sacral Nerve Stimulation (SNS) System in Patients With Symptoms of Overactive Bladder (OAB)	310	April 2024
NCT02577302[a]	Multi-center, Prospective, Randomized, Controlled, Non-Inferiority, Clinical Trial of Chronic Afferent Nerve Stimulation (CAN-Stim) of the Tibial Nerve Versus Sacral Nerve Stimulation (SNS) in the Treatment of Urinary Urgency Incontinence Resulting From Refractory Overactive Bladder (OAB)	200	Oct 2025
NCT05543382[a]	Cycling Study With the Axonics System	60	Feb 2024
NCT05064384[a]	Axonics SacRal NeuromodulaTIon System RegisTRY Study : ARTISTRY	300	Nov 2023
Unpublished			
NCT04710433	Non-invasive Sacral Nerve Stimulation in Children and Adolescents With Chronic Constipation: a case-control study on external neuromodulatory treatment	59	Dec 2021

NCT: national clinical trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2012 Input

In response to requests, input was received from four physician specialty societies and two academic medical centers while this policy was under review in 2012. Reviewers from two specialty societies and two academic medical centers provided opinions on the possible medical necessity of implantable leads for test stimulation, as part of a 2-stage process for device implantation. All four respondents supported the use of implantable leads for test stimulation as an alternative to percutaneous test stimulation for patients who had failed percutaneous test

stimulation and/or for patients with inconclusive percutaneous test stimulation. Reasons for support included a longer period of interrupted treatment with stage-1 stimulation due to less lead migration and a higher rate of positive tests compared with percutaneous test stimulation.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Urinary Disorders

American Urological Association

In 2019, the American Urological Association updated its guidelines on the diagnosis and treatment of overactive bladder.[44] The guidelines stated that sacral neuromodulation may be offered as a third-line treatment in carefully selected patients with severe refractory symptoms or into those who are not candidates for second-line therapy (e.g., oral antimuscarinics, oral β3-adrenoceptor agonists, transdermal oxybutynin) and are willing to undergo surgery (recommendation, evidence strength grade C).

American College of Obstetricians and Gynecologists

A 2015 practice bulletin on urinary incontinence (replaced practice bulletin number 63, 2005; reaffirmed in 2019) from the College stated, "sacral neuromodulation may be considered for patients with recalcitrant urinary urge incontinence who have failed other conservative measures, including bladder training, pelvic floor physical therapy with biofeedback, and pharmacologic treatment.".[45]

International Continence Society

In 2018, the International Continence Society published a best practice statement on the use of sacral neuromodulation.[46] The authors specified that the guideline recommendations applied primarily to the Interstim device and may or may not be applicable to future devices that have become available since that time. For both urinary and bowel disorders, first-line interventions include behavioral therapy, physical therapy, and medical management. Sacral neuromodulation can be offered to patients who fail or have an intolerance to first-line interventions. The guideline also states that sacral neuromodulation is appropriate for interstitial cystitis, bladder pain syndrome, Fowler's syndrome, voiding dysfunction, and nonobstructive urinary retention. However, there was a lack of evidence supporting the use of sacral neuromodulation for chronic pelvic pain unrelated to any of the aforementioned etiologies. For constipation, sacral neuromodulation should only be considered for patients who have had symptoms for at least 1 year, whose symptoms cannot be attributed to a mechanically correctable cause, and when conservative treatment has failed. Contraindications to sacral neuromodulation include lack of response during a therapeutic trial and pregnancy. Relative contraindications may include severe or rapidly progressive neurologic disease, abnormal sacral anatomy, anticipated need for magnetic resonance imaging below the head, and spinal cord injury.

National Institute for Health and Care Excellence

In 2020, NICE issued guidance on the Axonics sacral neuromodulation system for treating refractory overactive bladder.[47] The guidance states that the Axonics system should be considered an option for people with refractory overactive bladder. Similarly, 2004 guidance states that use of sacral nerve stimulation for urge incontinence and symptoms of urgency/frequency is supported by evidence of efficacy and safety.[48]

Fecal Disorders

National Institute for Health and Care Excellence

In 2007, the National Institute for Health and Care Excellence issued guidance on the management of fecal incontinence. The guidance was reviewed in 2014 and 2018, and no changes were made. The guidance has recommended:

> "A trial of temporary sacral nerve stimulation should be considered for people with fecal incontinence in whom sphincter surgery is deemed inappropriate… All individuals should be

informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. People with fecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success."[49]

American College of Gastroenterology

In its 2014 clinical guideline on the management of benign anorectal disorders, including fecal incontinence, the American College of Gastroenterology (ACG) found that "sacral nerve stimulation should be considered in [fecal incontinence] who do not respond to conservative therapy (strong recommendation, moderate quality of evidence)."[50] The 2021 update of these guidelines keep the recommendation for sacral nerve stimulation in patients with fecal incontinence refractory to medical therapy the same as in the 2014 version.[51] Additionally, due to a lack of evidence supporting efficacy and the risk of adverse events and complications, the 2021 ACG Panel makes a statement stating that sacral nerve stimulation "cannot be recommended in patients with constipation of any type."

American College of Obstetricians and Gynecologists

A 2019 practice bulletin (reaffirmed 2021) on fecal incontinence from the American College of Obstetricians and Gynecologists (ACOG) stated, "Sacral nerve stimulation can be considered as a surgical treatment option for women with fecal incontinence with or without anal sphincter disruption who have failed conservative treatments."[52]

American Society of Colon and Rectal Surgeons

In 2023, the American Society of Colon and Rectal Surgeons released an updated clinical practice guideline for the treatment of fecal incontinence.[53] They stated that "sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects (strength of recommendation, conditional; GRADE quality of evidence, low)."

In 2016, the Society released a clinical practice guideline for the management of constipation.[54] In this guideline, they stated "sacral neuromodulation may be an effective treatment for patients with chronic constipation and successful peripheral nerve evaluation test when conservative

measures have failed; however, it is not currently approved by the US Food and Drug Administration for this condition in the United States (Grade of Recommendation: Weak, based on moderate quality evidence, 2B)."

Chronic Pelvic Pain

American College of Obstetricians and Gynecologists

A 2020 practice bulletin (reaffirmed 2023) on chronic pelvic pain from ACOG does not mention sacral nerve stimulation or modulation.[55]

Medicare National Coverage

In 2002, the Centers for Medicare & Medicaid Services covers SNS for the "treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention."[56] SNS "involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered."

"The following limitations for coverage apply to all three indications:

- "Patients must be refractory to conventional therapy...and be appropriate surgical candidates such that implantation with anesthesia can occur.
- "Patients with stress incontinence, urinary obstruction, and specific neurologic diseases...that are associated with secondary manifestations...are excluded.
- "Patients must have had successful test stimulation in order to support subsequent implantation. Before patients are eligible for permanent implantation, they must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries."

Regulatory Status

In 1997, the Interstim Sacral Nerve Stimulation system (Medtronic) was approved by the US 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 Medtronic 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.

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 FDA for 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.

Note: This policy does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Pelvic floor stimulation is addressed in a separate in policy (see **Related Policies**).

This policy does not address devices that provide direct SNS in patients with spinal cord injuries. The VOCARE Bladder System/ FineTech Brindley Bladder Control System, a stimulator implanted in the sacral anterior nerve roots, is one device intended for patients with complete spinal cord injury and neurogenic bladder.

References

1. Food and Drug Administration (FDA). Summary of Safety and Effectiveness: Medtronic Interstim System for Urinary Control. **http://www.accessdata.fda.gov/cdrh_docs/pdf/P970004S004b.pdf**. Accessed May 13, 2024.
2. Weil EH, Ruiz-Cerdá JL, Eerdmans PH, et al. Sacral root neuromodulation in the treatment of refractory urinary urge incontinence: a prospective randomized clinical trial. Eur Urol. Feb 2000; 37(2): 161-71. PMID 10705194
3. Siegel S, Noblett K, Mangel J, et al. Results of a prospective, randomized, multicenter study evaluating sacral neuromodulation with InterStim therapy compared to standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. Neurourol Urodyn. Mar 2015; 34(3): 224-30. PMID 24415559
4. Noblett K, Siegel S, Mangel J, et al. Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. Neurourol Urodyn. Feb 2016; 35(2): 246-51. PMID 25546568
5. Amundsen CL, Richter HE, Menefee SA, et al. OnabotulinumtoxinA vs Sacral Neuromodulation on Refractory Urgency Urinary Incontinence in Women: A Randomized Clinical Trial. JAMA. Oct 04 2016; 316(13): 1366-1374. PMID 27701661
6. Chartier-Kastler E, Normand LL, Ruffion A, et al. Sacral Neuromodulation with the InterStim System for Overactive Bladder: 3-Year Results from the French Prospective, Multicenter, Observational SOUNDS Study. Eur Urol Focus. Sep 2022; 8(5): 1399-1407. PMID 34334342
7. Pezzella A, McCrery R, Lane F, et al. Two-year outcomes of the ARTISAN-SNM study for the treatment of urinary urgency incontinence using the Axonics rechargeable sacral neuromodulation system. Neurourol Urodyn. Feb 2021; 40(2): 714-721. PMID 33508155
8. Blok B, Van Kerrebroeck P, de Wachter S, et al. Two-year safety and efficacy outcomes for the treatment of overactive bladder using a long-lived rechargeable sacral neuromodulation system. Neurourol Urodyn. Apr 2020; 39(4): 1108-1114. PMID 32243625
9. Groen J, Blok BF, Bosch JL. Sacral neuromodulation as treatment for refractory idiopathic urge urinary incontinence: 5-year results of a longitudinal study in 60 women. J Urol. Sep 2011; 186(3): 954-9. PMID 21791355
10. White WM, Mobley JD, Doggweiler R, et al. Incidence and predictors of complications with sacral neuromodulation. Urology. Apr 2009; 73(4): 731-5. PMID 19193415
11. Thaha MA, Abukar AA, Thin NN, et al. Sacral nerve stimulation for faecal incontinence and constipation in adults. Cochrane Database Syst Rev. Aug 24 2015; 2015(8): CD004464. PMID 26299888
12. Thin NN, Horrocks EJ, Hotouras A, et al. Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence. Br J Surg. Oct 2013; 100(11): 1430-47. PMID 24037562
13. Tan E, Ngo NT, Darzi A, et al. Meta-analysis: sacral nerve stimulation versus conservative therapy in the treatment of faecal incontinence. Int J Colorectal Dis. Mar 2011; 26(3): 275-94. PMID 21279370
14. Maeda Y, Matzel K, Lundby L, et al. Postoperative issues of sacral nerve stimulation for fecal incontinence and constipation: a systematic literature review and treatment guideline. Dis Colon Rectum. Nov 2011; 54(11): 1443-60. PMID 21979192
15. Tjandra JJ, Chan MK, Yeh CH, et al. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. Dis Colon Rectum. May 2008; 51(5): 494-502. PMID 18278532
16. Leroi AM, Parc Y, Lehur PA, et al. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. Ann Surg. Nov 2005; 242(5): 662-9. PMID 16244539
17. Wexner SD, Coller JA, Devroede G, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. Ann Surg. Mar 2010; 251(3): 441-9. PMID 20160636

18. Mellgren A, Wexner SD, Coller JA, et al. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum. Sep 2011; 54(9): 1065-75. PMID 21825885

19. Hull T, Giese C, Wexner SD, et al. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. Dis Colon Rectum. Feb 2013; 56(2): 234-45. PMID 23303153

20. Altomare DF, Giuratrabocchetta S, Knowles CH, et al. Long-term outcomes of sacral nerve stimulation for faecal incontinence. Br J Surg. Mar 2015; 102(4): 407-15. PMID 25644687

21. Leo CA, Thomas GP, Bradshaw E, et al. Long-term outcome of sacral nerve stimulation for faecal incontinence. Colorectal Dis. Dec 2020; 22(12): 2191-2198. PMID 32954658

22. Desprez C, Damon H, Meurette G, et al. Ten-year Evaluation of a Large Retrospective Cohort Treated by Sacral Nerve Modulation for Fecal Incontinence: Results of a French Multicenter Study. Ann Surg. Apr 01 2022; 275(4): 735-742. PMID 32740249

23. De Meyere C, Nuytens F, Parmentier I, et al. Five-year single center experience of sacral neuromodulation for isolated fecal incontinence or fecal incontinence combined with low anterior resection syndrome. Tech Coloproctol. Sep 2020; 24(9): 947-958. PMID 32556866

24. Picciariello A, Rinaldi M, Dibra R, et al. Ageing with sacral nerve modulation for fecal incontinence: how many patients get benefit after more than 10 years?. Updates Surg. Feb 2022; 74(1): 185-191. PMID 34982410

25. Jottard K, Van den Broeck S, Komen N, et al. Treatment of Fecal Incontinence With a Rechargeable Sacral Neuromodulation System: Efficacy, Clinical Outcome, and Ease of Use-Six-Month Follow-Up. Neuromodulation. Oct 2021; 24(7): 1284-1288. PMID 33107663

26. Pauwels N, Willemse C, Hellemans S, et al. The role of neuromodulation in chronic functional constipation: a systematic review. Acta Gastroenterol Belg. 2021; 84(3): 467-476. PMID 34599572

27. Pilkington SA, Emmett C, Knowles CH, et al. Surgery for constipation: systematic review and practice recommendations: Results V: Sacral Nerve Stimulation. Colorectal Dis. Sep 2017; 19 Suppl 3: 92-100. PMID 28960926

28. Thomas GP, Dudding TC, Rahbour G, et al. Sacral nerve stimulation for constipation. Br J Surg. Jan 2013; 100(2): 174-81. PMID 23124687

29. Knowles CH, Thin N, Gill K, et al. Prospective randomized double-blind study of temporary sacral nerve stimulation in patients with rectal evacuatory dysfunction and rectal hyposensitivity. Ann Surg. Apr 2012; 255(4): 643-9. PMID 22418005

30. Zerbib F, Siproudhis L, Lehur PA, et al. Randomized clinical trial of sacral nerve stimulation for refractory constipation. Br J Surg. Feb 2017; 104(3): 205-213. PMID 27779312

31. Dinning PG, Hunt L, Patton V, et al. Treatment efficacy of sacral nerve stimulation in slow transit constipation: a two-phase, double-blind randomized controlled crossover study. Am J Gastroenterol. May 2015; 110(5): 733-40. PMID 25895520

32. Kamm MA, Dudding TC, Melenhorst J, et al. Sacral nerve stimulation for intractable constipation. Gut. Mar 2010; 59(3): 333-40. PMID 20207638

33. Maeda Y, Lundby L, Buntzen S, et al. Sacral nerve stimulation for constipation: suboptimal outcome and adverse events. Dis Colon Rectum. Jul 2010; 53(7): 995-9. PMID 20551750

34. Tirlapur SA, Vlismas A, Ball E, et al. Nerve stimulation for chronic pelvic pain and bladder pain syndrome: a systematic review. Acta Obstet Gynecol Scand. Aug 2013; 92(8): 881-7. PMID 23710833

35. Martellucci J, Naldini G, Carriero A. Sacral nerve modulation in the treatment of chronic pelvic pain. Int J Colorectal Dis. Jul 2012; 27(7): 921-6. PMID 22203519

36. Siegel S, Paszkiewicz E, Kirkpatrick C, et al. Sacral nerve stimulation in patients with chronic intractable pelvic pain. J Urol. Nov 2001; 166(5): 1742-5. PMID 11586214

37. Greig J, Mak Q, Furrer MA, et al. Sacral neuromodulation in the management of chronic pelvic pain: A systematic review and meta-analysis. Neurourol Urodyn. Apr 2023; 42(4): 822-836. PMID 36877182

38. Baxter C, Kim JH. Contrasting the percutaneous nerve evaluation versus staged implantation in sacral neuromodulation. Curr Urol Rep. Sep 2010; 11(5): 310-4. PMID 20535593

39. Leong RK, De Wachter SG, Nieman FH, et al. PNE versus 1st stage tined lead procedure: a direct comparison to select the most sensitive test method to identify patients suitable for sacral neuromodulation therapy. Neurourol Urodyn. Sep 2011; 30(7): 1249-52. PMID 21404317

40. Scheepens WA, Van Koeveringe GA, De Bie RA, et al. Long-term efficacy and safety results of the two-stage implantation technique in sacral neuromodulation. BJU Int. Dec 2002; 90(9): 840-5. PMID 12460343

41. Marcelissen TA, Leong RK, de Bie RA, et al. Long-term results of sacral neuromodulation with the tined lead procedure. J Urol. Nov 2010; 184(5): 1997-2000. PMID 20850820

42. Borawski KM, Foster RT, Webster GD, et al. Predicting implantation with a neuromodulator using two different test stimulation techniques: A prospective randomized study in urge incontinent women. Neurourol Urodyn. 2007; 26(1): 14-8. PMID 17123297

43. Bannowsky A, Wefer B, Braun PM, et al. Urodynamic changes and response rates in patients treated with permanent electrodes compared to conventional wire electrodes in the peripheral nerve evaluation test. World J Urol. Dec 2008; 26(6): 623-6. PMID 18629503

44. Diagnosis and treatment of non-neurogenic overactive bladder (OAB) in adults: an AUA/SUFU Guideline (2019). **https://www.auanet.org/guidelines-and-quality/guidelines/overactive-bladder-(oab)-guideline**. Accessed May 13, 2024.

45. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. Nov 2015; 126(5): e66-e81. PMID 26488524

46. Goldman HB, Lloyd JC, Noblett KL, et al. International Continence Society best practice statement for use of sacral neuromodulation. Neurourol Urodyn. Jun 2018; 37(5): 1823-1848. PMID 29641846

47. National Institute for Health and Care Excellence (NICE). Axonics sacral neuromodulation system for treating refractory overactive bladder [MTG50]. 2020; **https://www.nice.org.uk/guidance/mtg50**. Accessed May 13, 2024.

48. National Institute for Health and Care Excellence (NICE). Sacral nerve stimulation for urge incontinence and urgency-frequency. IPG64. **https://www.nice.org.uk/guidance/ipg64**. Accessed May 13, 2024.

49. National Institute for Health and Care Excellence (NICE). Faecal incontinence in adults: management [CG49]. 2007; **https://www.nice.org.uk/guidance/CG49**. Accessed May 13, 2024.

50. Wald A, Bharucha AE, Cosman BC, et al. ACG clinical guideline: management of benign anorectal disorders. Am J Gastroenterol. Aug 2014; 109(8): 1141-57; (Quiz) 1058. PMID 25022811

51. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. Am J Gastroenterol. Oct 01 2021; 116(10): 1987-2008. PMID 34618700

52. ACOG Practice Bulletin No. 210: Fecal Incontinence. Obstet Gynecol. Apr 2019; 133(4): e260-e273. PMID 30913197

53. Bordeianou, L. G., Thorsen, A. J., Keller, D. S., et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Fecal Incontinence. 2023. Diseases of the colon and rectum, 66(5), 647-661. **https://doi.org/10.1097/DCR.0000000000002776** Accessed May 13, 2024.

54. Paquette IM, Varma M, Ternent C, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Evaluation and Management of Constipation. Dis Colon Rectum. Jun 2016; 59(6): 479-92. PMID 27145304

55. Chronic Pelvic Pain: ACOG Practice Bulletin, Number 218. Obstet Gynecol. Mar 2020; 135(3): e98-e109. PMID 32080051

56. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for SACRAL NERVE Stimulation For Urinary Incontinence (230.18). 2002; **https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=249**. Accessed May 13, 2024.

History

Date	Comments
03/02/99	Add to Surgery Section - New Policy
01/04/00	Replace Policy - Content updated; policy statement revised to include new FDA approved indications.
09/21/00	Replace Policy - Policy updated with reference to 2000 TEC assessment; policy statement unchanged.
04/09/02	Replace Policy - CPT code; policy statement unchanged.
05/13/03	Replace Policy - Policy updated; policy statement unchanged. New references added.
09/14/04	Replace Policy - Policy revised and expanded to address neuromodulation to treat fecal incontinence and constipation as investigational.
08/09/05	Replace Policy - Policy updated with literature search; no changes in policy statement.
02/06/06	Codes updated - No other changes.
06/09/06	Disclaimer and Scope update - No further changes.
04/10/07	Cross Reference Update - No other changes.
11/13/07	Replace Policy - Policy updated with literature search; no changes in policy statement; references added; codes added
05/13/08	Code Updates - Code 787.6 added.
07/14/09	Replace Policy - Policy updated with literature search. Policy statement updated and clarified with selection criteria. References added.
08/10/10	Replace Policy - Policy updated with literature review through March 2010; references added and reordered. Policy statement on fecal incontinence has been changed from "investigational" to "may be medically necessary under specific conditions."
07/12/11	Replace Policy - Policy updated with literature search through March 2011. References 7, 24, 26, 27, 29, 30, 34, and 36 added; other references reordered or removed. Policy statements unchanged. ICD-10 codes added to policy.
09/23/11	Related Policies updated; 2.01.27 added.
06/12/12	Replace policy. Policy updated with literature search through February 2012. Rationale and Policy Guidelines re-written. References 5, 13, 14 and 19-24 added; other references reordered or removed. Clinical input added. Implantable lead stimulation added as alternative stimulation method for eligible patients within medically necessary policy statements. Medically necessary policy statement for urinary incontinence changed to 2-part statement (has criteria for test stimulation and for permanent implantation). Material on methods of trial test stimulation added to

Date	Comments
	Background and Rationale sections. Title changed to Sacral Nerve Neuromodulation/Stimulation. Code 64590 removed as it does not apply to this policy.
09/28/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014. Add Related Policy 8.03.01.
06/10/13	Replace policy. Policy updated with literature search through March 13, 2013. Length of successful percutaneous test stimulation in medically necessary statements changed from at least 2 weeks to at least 1 week. Fecal incontinence policy statement separated into 2 statements; 1 on trial stimulation and 1 on permanent implantation. Edits made to statements so that criteria for fecal and urinary incontinence are similar, when applicable. References 12, 13, 16, 17 and 20 added; other references renumbered or removed.
01/28/14	Minor updated. CPT codes 95972 and 95973 listed within the Policy Guidelines extended to the Coding table to reflect consistency. Scope updated to indicate that this policy not part of Medicare Advantage.
03/21/14	Update Related Policies. Delete 7.01.106 and replace with 7.01.553.
06/09/14	Annual Review. Policy updated with literature review through March 5, 2014. References 5, 9, 12, 21, 30-31, and 34-35 added. Overactive bladder added to medically necessary statement on urinary incontinence. ICD-9 and ICD-10 diagnosis and procedure codes removed; this is performed inpatient.
06/27/14	Update Related Policies. Change title to 1.01.17.
09/08/14	Interim Update. Clarification added as #6 criteria under subheading "A" Fecal Incontinence. Specified the length of time after surgery when a trial of sacral nerve neurostimulation may be considered medically necessary. No new references added. Policy statement clarified as noted.
04/17/15	Update Related Policies. Remove 7.01.553 as it was archived.
09/08/15	Annual Review. In both subheadings titled "B.2" the medically necessary statements that were changed from 1 week to "at least 48 hours" for the trial stimulation period. Policy updated with literature review through June 8, 2015; references 6, 16, 20, and 32 added. Policy statements revised as noted.
12/16/15	Update Related Policies. Remove 2.01.58 as it is archived.
01/29/16	Minor update. Added HCPCS code L8679.
06/01/16	Annual Review, approved May 10, 2016. Policy updated with literature review; reference added. No change to the policy statement. Updated the coding table.
03/01/17	Coding Update. Removed CPT code 95973 as it was deleted as of 01/01/2016.
04/01/17	Annual review, approved March 14, 2017. Policy updated with literature review through November 7, 2016; references 7, 10, and 22 added. Removed HCPCS code E1399 and CPT code 64595. Policy statements unchanged.

Date	Comments
08/25/17	Coding update, removed CPT codes 95970 and 95972. Moved into new format, no changes to policy statement.
02/01/18	Interim Review, approved January 30, 2018. Added clarity for neurologic condition. Intent of policy unchanged.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; reference 40 added. Minor editorial changes to the Policy section; statements unchanged. Removed CPT codes 64585 and 64590.
04/01/19	Minor update, added Documentation Requirements section.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; reference 39 removed; reference added. Policy statements unchanged. Added HCPCS code L8684.
02/01/20	Coding update, added CPT codes 64585, 64590, and 64595.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through February 2020; references updated. Policy statements unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 5, 2021; references updated. Policy statements unchanged. Added HCPC codes C1767 and C1778.
01/01/22	Coding update, updated description for CPT 64581.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 4, 2022; references added. Policy statements unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through February 14, 2023; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/24	Coding update. Added new CPT code 0786T and 0787T.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 13, 2024; references added. Policy statements unchanged.
12/01/24	Interim Review, approved November 11, 2024. Minor edits and reformatting done for greater clarity; policy intent unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.