

## MEDICAL POLICY – 7.01.69

## Sacral Nerve Neuromodulation/Stimulation

BCBSA Ref. Policy: 7.01.69

Effective Date: July 1, 2023

Last Revised: Jan. 1, 2024

Replaces: N/A

## RELATED MEDICAL POLICIES:

8.03.01 Functional Neuromuscular Electrical Stimulation

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
<b>Urinary Incontinence and Non-obstructive Retention</b>	
<b>Sacral nerve neuromodulation</b>	<p><b>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:</b></p> <ul style="list-style-type: none"> <li>• There is a diagnosis of at least one of the following: <ul style="list-style-type: none"> <li>○ Urge incontinence</li> <li>○ Urgency-frequency syndrome</li> <li>○ Nonobstructive urinary retention</li> <li>○ Overactive bladder (see <a href="#">Definition of Terms</a>)</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• There is documented failure or intolerance to at least 2 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)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The individual is an appropriate surgical candidate</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition (such as multiple sclerosis or diabetic neuropathy)</li> </ul>
<b>Permanent implantation, sacral nerve neuromodulation device</b>	<p><b>Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in individuals who meet ALL of the following criteria:</b></p> <ul style="list-style-type: none"> <li>• All of the criteria above are met</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours</li> </ul>
<b>Fecal Incontinence</b>	
<b>Sacral nerve neuromodulation</b>	<p><b>A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted</b></p>



Service	Medical Necessity
	<p><b>lead may be considered medically necessary in individuals who meet all of the following criteria:</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The individual is an appropriate surgical candidate</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition (such as multiple sclerosis or diabetic neuropathy)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul>
<p><b>Permanent implantation, sacral nerve neuromodulation device</b></p>	<p><b>Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in individuals who meet all of the following criteria:</b></p> <ul style="list-style-type: none"> <li>• All of the criteria above are met</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.</li> </ul>

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

Documentation Requirements
<p><b>The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis/condition</li> <li>• History and physical examination documenting the severity of the condition</li> <li>• Conventional conservative therapies that have been tried and failed</li> <li>• Any history of rectal surgery</li> <li>• Any neurologic conditions or history of spinal cord injury</li> <li>• If request is for permanent placement, results of trial</li> </ul>

## Coding

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

Code	Description
<b>CPT</b>	
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)
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)

Code	Description
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
<b>HCPCS</b>	
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

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## 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 19, 2023).

## Evidence Review

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### 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 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 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
<b>Ongoing</b>			
<a href="#">NCT03139734</a>	Sacral Neuromodulation for Pelvic Pain Associated with Endometriosis	50	May 2022
<a href="#">NCT03811821</a>	Comparative Effects of Biofeedback, Sacral Nerve Stimulation, and Injectable Bulking Agents for Treatment of Fecal Incontinence: The Fecal Incontinence Treatment Study (FIT) Study	285	Dec 2025



NCT No.	Trial Name	Planned Enrollment	Completion Date
<a href="#">NCT04506866<sup>a</sup></a>	Evaluation of InterStim Micro System Performance and Safety (ELITE) to Confirm Long-Term Outcomes - Post Market Clinical Follow-Up Study	148	Nov 2024
<a href="#">NCT04713085</a>	Sacral Nerve Stimulation in Children and Adolescents With Chronic Constipation: a Case-control Study on Invasive and Non-invasive Neuromodulatory Treatment	30	Dec 2023
<a href="#">NCT04232696<sup>a</sup></a>	Clinical Study of Neurasper's Implantable Sacral Nerve Stimulation (SNS) System in Patients With Symptoms of Overactive Bladder (OAB)	310	April 2024
<a href="#">NCT02577302<sup>a</sup></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 2024
<a href="#">NCT05543382<sup>a</sup></a>	Cycling Study With the Axonics System	60	Jun 2023
<a href="#">NCT05064384<sup>a</sup></a>	Axonics SacRal Neuromodulation System Registry Study : ARTISTRY	300	Nov 2023
<a href="#">NCT03327948<sup>a</sup></a>	Axonics SacRal Neuromodulation System for Urinary Urgency Incontinence Treatment (ARTISAN-SNM)	145	Jun 2020 (active, not recruiting)
<b>Unpublished</b>			
<a href="#">NCT04710433</a>	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 U.S. professional society, an international society with U.S. representation, or 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.<sup>43</sup> 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  $\beta$ 3-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." <sup>44</sup>

## **International Continence Society**

In 2018, the International Continence Society published a best practice statement on the use of sacral neuromodulation. <sup>45</sup> 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. <sup>46</sup> 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. <sup>47</sup>



## 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."<sup>48</sup>

### 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)."<sup>49</sup> 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.<sup>50</sup> 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."<sup>51</sup>



## **American Society of Colon and Rectal Surgeons**

In 2015, the American Society of Colon and Rectal Surgeons released a clinical practice guideline for the treatment of fecal incontinence.<sup>52</sup> They stated that "sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects (Grade of Recommendation: Strong, based on moderate-quality evidence, 1B)."

In 2016, the Society released a clinical practice guideline for the management of constipation.<sup>46</sup> 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.<sup>54</sup>

## **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."<sup>55</sup> 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 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 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 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.

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## 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.



Date	Comments
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 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.



Date	Comments
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.
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.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.



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