

VHA Office of Integrated Veteran Care Clinical Determination and Indication Sacral Neuromodulation

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I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications for the Indications for Sacral Neuromodulation / Sacral Nerve Stimulation

Sacral neuromodulation, also known as sacral nerve stimulation, a minimally invasive procedure, is indicated for the following conditions:

- Urge urinary incontinence
- Urinary retention
- Urinary urgency and frequency (urgency-frequency syndrome)
- Fecal incontinence

i. Indications for Sacral Neuromodulation for Urinary Incontinence, Retention, and Urgency/Frequency

A trial or **temporary** sacral nerve stimulator will be considered **medically necessary** when **ALL** the following criteria are met:

- An established diagnosis of at least one of the following conditions:
 - Urinary incontinence
 - Non-obstructive urinary retention
 - Urinary urgency-frequency
- Symptoms are clinically significant and affect work and/or activities of daily living (ADLs)

- Progressed and failed conventional first line and second line interventions
 - First line intervention – behavioral modification
 - Second line intervention – pharmacological management

A **permanent** sacral nerve stimulator is considered medically necessary when **ALL** the following criteria are met:

- The Veteran has met criteria for a trial of temporary sacral nerve stimulation
- The Veteran has demonstrated a successful trial of the temporary sacral nerve stimulator
 - For urinary incontinence – at least a 50% reduction in one of the following: daily incontinence episodes, severity of the episodes, or the number of pads/diapers used per day
 - For non-obstructive urinary retention – at least a 50% reduction in catheterized volume/catheterization frequency
 - For urinary urgency-frequency – at least a 50% reduction in the number of voids daily, or a 50% increase in volume voided per micturition

Note: Pre- and post-trial voiding diaries are highly recommended to closely document efficacy of the treatment and maintain high quality care for Veterans.

ii. **Indications for Sacral Neuromodulation for Fecal Incontinence**

A trial or **temporary** sacral nerve stimulator will be considered **medically necessary** when **ALL** the following criteria are met:

- An established diagnosis of fecal incontinence
 - Incontinent episodes average greater than 2 per week for 6 months or for more than 12 months after vaginal childbirth
 - Incontinence not amenable to surgical intervention as determined by a colorectal or urogynecologic surgeon
 - Occult fecal incontinence
- Symptoms are clinically significant and affect work and/or ADLs

- Progressed and failed conventional first line and second line interventions
 - First line intervention – dietary modification and the addition of bulking fiber supplements (e.g., psyllium)
 - Second line intervention – pharmacological management for those experiencing loose stool/diarrhea

Note: Pelvic floor exercises with a trained pelvic floor physical therapist may provide some benefit as a first line intervention.

A **permanent** sacral nerve stimulator is considered medically necessary when **ALL** the following criteria are met:

- The Veteran has met the criteria for a trial or temporary sacral nerve stimulator
- The Veteran has demonstrated a successful trial (at least a 50% improvement in symptoms) with the temporary sacral nerve stimulator

Note: Pre- and post-trial bowel movement diaries are highly recommended to closely document efficacy of the treatment and maintain high quality care for Veterans.

b. Limitations/Exclusions

Conditions/indications for which sacral neuromodulation is **not medically necessary** include, but are not limited to, the following:

- Stress incontinence
- Obstructive urinary retention
- Congenital anorectal malformation
- Active inflammatory bowel disease
- Fecal incontinence related to a neurologic condition such as peripheral neuropathy or complete spinal cord injury (i.e., there is no nerve function below the site of injury, resulting in loss of complete function)

For all conditions/indications not listed in section II.a. of this document, sacral neuromodulation is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

c. Description of Treatment

Sacral neuromodulation, also known as sacral nerve stimulation, is a minimally invasive therapy indicated to treat urinary incontinence, urinary retention, urinary urgency-frequency, and fecal incontinence. A 4-wire lead with 4 metal contacts is surgically placed transcutaneously in the lower sacral area and connected to a generator placed in the adjacent buttock that produces mild electrical impulses that stimulate the S3 nerve which, in turn, results in modulation of neural circuits in the spinal cord and brain via afferent signaling that normalizes voiding and defecatory functions.

A temporary device is initially placed to determine effectiveness in treating the symptoms. During the temporary trial, the patient will record their bowel and/or bladder events during the trial period. These results help determine if permanent device placement is considered medically necessary.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background Information

Urinary Incontinence

Urinary incontinence affects all genders and is defined as the loss of bladder control, resulting in uncontrolled leaking of urine. It is also known as overactive bladder and symptoms include urinary urgency, urinary frequency, and urge incontinence with or without nocturia.

Both the brain and the bladder control urinary function. Nerves that branch off from the sacral nerve control the bladder and the sphincter muscles, which keep the urethra closed.

There are different types of urinary incontinence including:

- Stress Urinary Incontinence
 - The most common type and usually due to weakened pelvic muscles
 - Urine leakage may occur with normal activities such as exercise, walking, bending, lifting, sneezing and coughing
 - Conservative therapy for this type of urinary incontinence includes Kegel exercises to strengthen the pelvic floor, lifestyle modifications, urethral bulking, and in some cases surgery

- Overactive Bladder (Urge Incontinence)
 - Another common type of urinary incontinence, characterized by a sudden, intense urge to urinate, even if the bladder is not full, followed by an involuntary loss of urine
 - The patient often needs to urinate many times during the day and night
 - More common in patients with prostate problems and patients after menopause
 - Common treatments include lifestyle modifications, medications that relax the bladder muscle, peripheral neuromodulation, Botox injections, and sometimes surgery
- Overflow Incontinence
 - Characterized by frequent or constant dribbling of urine due to more urine produced than the bladder is able to hold or an overfull bladder
 - May be caused by blockage of flow or the bladder's inability to contract and squeeze urine out
 - This type of incontinence is more common in patients with prostate problems or those who have had prostate surgery
- Insensible Urinary Incontinence
 - Also known as incontinence without sensory awareness
 - A complaint of urinary incontinence where the individual is aware of urine leakage but unaware of how or when it occurred
- Mixed Incontinence
 - A mix of stress urinary incontinence and urge incontinence

Fecal Incontinence

Fecal incontinence, also called accidental bowel leakage, is the involuntary and accidental passing of stool (solid or liquid) from the anus. There may or may not be an urge to have a bowel movement and patients are unable to control their bowel movements.

There are many causes of fecal incontinence, including digestive tract disorders, chronic diseases, injury, and surgery. Some examples include pelvic floor muscle injury and/or weakness, nerve damage, neurologic diseases (e.g., dementia, multiple sclerosis, stroke, diabetes type II, etc.), hemorrhoids, rectal prolapse, and many others.

Common treatments may include diet changes, over-the-counter medications, bowel training, and pelvic floor muscle exercises (Kegels). Changing a diet may help prevent or relieve fecal incontinence and may include food avoidance and/or modifications to foods and drinks ingested.

b. Research, Clinical Trials, and Evidence Summaries

Wexner et al. (2010) conducted a multicentered, prospective, non-randomized trial for the sacral nerve stimulator with 133 patients. Patients were required to keep a diary of their bowel movements and the Medtronic MDT-301 SNS was used for implantation. Patients included in the study had greater than six months of bowel fecal incontinence and greater than two episodes per week. Patients who qualified for the implant had previously undergone a temporary test stimulation period for 10-14 days and if this resulted in greater than a 50% decrease in incontinence, a permanent sacral nerve stimulator was implanted. The study found a 90% success in decrease of fecal incontinence in test stimulation and after implantation of the sacral nerve stimulator, there was an 83% success rate reported at 12 months and an 84% success rate reported at 24 months.

Thaha et al. (2015) reviewed randomized and quasi-randomized trials for sacral nerve stimulator therapy for fecal incontinence or constipation in adults. In the review there were a total of 219 participants for fecal incontinence and 61 participants for constipation. In all studies evaluated for fecal incontinence, when the patient chose the “on” setting of the sacral nerve stimulator, they had decreased episodes of incontinence ranging from 50% to 88%. For constipation, one study showed a 150% increase in frequency, but the other study showed no improvement in frequency. Adverse effects of device implantation were noted in only four patients including electrode problems or hematomas. Upon conclusion of the review, sacral nerve stimulators showed to improve fecal incontinence but did not show evidence of improvement for constipation.

Leo et al. (2020) reviewed a prospective database to determine the long-term outcome of the sacral nerve stimulator implanted device. The review looked at 256 patients from 1996 to 2014. Only patients that had undergone the sacral nerve stimulator implant for fecal incontinence were included in the study results. At the 6-month interval, 50% of the patients had a reduction of fecal incontinence by more than 50%. The long-term improvement was noted that 60% of those that received the implant had some reduction in fecal incontinence, but also noted that there was a significant reduction in efficacy over time, believed to be related to underlying causes. Of the 256 patients that received the implant, 61 had some form of complication with some requiring explanation, the most common complication was the need to change the stimulator’s settings. Other complications included infections, pain, numbness bleeding and revisional surgery. The study concluded that the long-term usage of the sacral nerve stimulator device is effective and durable.

Siegel et al. (2014) conducted a prospective, randomized, multicenter trial to evaluate the six-month success rate of sacral neuromodulation versus standard medical therapy for overactive bladder. The study included 147 subjects and results showed there was significantly greater therapeutic success in the group of patients receiving sacral neuromodulation, compared to the group receiving standard medical therapy. The team concluded that sacral neuromodulation has shown to be safe and effective for patients with overactive bladder experiencing mild to moderate symptoms.

Van Kerrebroeck et al. (2012) reviewed available literatures on sacral neuromodulation to review the technique, indications, results, and working mechanism of sacral neuromodulation for lower urinary tract dysfunction. The team highlighted the fact that sacral neuromodulation is a minimally invasive technique and has shown to be effective in about 70% of patients with a permanent device. The team concluded that sacral neuromodulation is a safe and effective therapy for various forms of lower urinary tract dysfunction and should be the first choice after failure of maximal conservative therapy.

Multiple studies have shown that sacral neuromodulation is an effective therapy for treating both urinary and fecal incontinence. Literature reviewed have shown that sacral neuromodulation is a safe and effective treatment for both urinary and fecal incontinence.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. Multiple sacral nerve stimulation devices have received Premarket Approval from the FDA and is indicated for use in the following:

- 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
- The treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the [FDA Devices database](#).

d. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

NCD Number	Name	Effective Date
230.18	Sacral Nerve Stimulation for Urinary Incontinence	01/01/2002

LCD Number	Contractor	Original/Revision Effective Date
L39543	Palmetto GBA	11/05/2023

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

e. TRICARE Policy Manual

Available TRICARE coverage determinations are listed below as a resource. VA and TRICARE are governed by separate laws and regulations; thus, VA coverage determinations may be different.

[TRICARE Policy Manual 6010.60-M, Chapter 4, Section 14.1](#)

[TRICARE Policy Manual 6010.60-M, Chapter 4, Section 20.1](#)

IV. Definitions

Term	Definition
Afferent Signaling	Afferent neurons that transmit signals from the sensory receptors in the periphery to the central nervous system
Anorectal Incontinence	The area of the anus and rectum The involuntary loss of bowel and/or bladder control resulting in leakage of fecal matter and/or urine
Micturition	The action of urinating
Neuromodulation	Therapies that target specific areas of the nervous system to help manage pain or modify abnormal functions of the body
Nocturia	Frequent urination at night
Peripheral Nerve	Part of the peripheral nervous system and connected to the brain and spinal cord, which provides motor and sensory function to the entire body
Prolapse	A term to describe any body part that has fallen from the normal position in the body, usually due to weakened or deteriorated muscles that normally support the body part

V. References

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VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	