

OHCA Guideline

Medical Procedure Class:	Sacral Nerve Stimulator for Urinary Incontinence and Fecal Incontinence
Initial Implementation Date:	January 5, 2015
Last Review Date:	May 2021
Effective Date:	September 2021
Next Review/Revision Date:	September 2024
* This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect, or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria	
Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
Description	
<p>Sacral nerve stimulation (SNS) is a pulse generator device that transmits electrical impulses to the sacral nerve through an implanted wire. SNS is the implantation of a permanent device that stimulates the sacral nerves and helps to control bladder function and fecal incontinence in members who have failed behavioral and/or pharmacologic therapies. SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates</p>	
CPT Codes Covered Requiring Prior Authorization (PA)	
<p>64561 - Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including imaging guidance, if performed</p> <p>64581 - Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</p> <p>64590 - Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver</p> <p>64595 - Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</p> <p>95972 – Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional</p>	
<p>Prior Authorization is required for BOTH temporary testing stimulation and permanent implantation of the Sacral Nerve Stimulator and Electrodes.</p>	

Approval Criteria

INDICATIONS

I. Treatment of Urge Urinary Incontinence and/or Urge-Frequency Incontinence:

- A.** Prior to permanent sacral nerve stimulator implantation, a **screening trial** of sacral nerve stimulation is considered medically necessary for the treatment of urge urinary incontinence or symptoms of urge-frequency when all of the following criteria are met:
1. The member has experienced urge UI or symptoms of urge-frequency for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); **AND**
 2. Pharmacotherapies (i.e., at least 2 different anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant) as well as behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management) have failed; **AND**
 3. The member is able to demonstrate adequate ability to record **voiding diary** data such that clinical results of the implant testing procedure can be properly evaluated.
- B.** Permanent sacral nerve stimulator implantation is considered medically necessary for the treatment of urge urinary incontinence or symptoms of urge-frequency when **all** of the criteria above (IA1, 2 & 3) are met **and** the test stimulation of the device has provided at least a 50% improvement in symptoms. Improvement is measured through **voiding diaries**.
- C.** A current member-maintained intake, output, and symptoms **voiding diary** is required to be submitted with the Screening Trial PAR **and** it is required to submit another member maintained **voiding diary** completed during the trial (3-4days) with the Permanent SNS implantation PAR to evaluate the effectiveness of the trial.

II. Treatment of Non-Obstructive Urinary Retention:

- A.** Prior to permanent sacral nerve stimulator implantation, a **screening trial** of sacral nerve stimulation is considered medically necessary for the treatment of non-obstructive urinary retention when **all** of the following criteria are met:
1. Member has experienced urinary retention for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); **AND**
 2. Pharmacotherapies (e.g., alpha blockers, cholinergics, and antibiotics for urinary tract infections) as well as intermittent catheterization have failed or are not well tolerated; **AND**
 3. The member is able to demonstrate adequate ability to record **voiding diary** data such that clinical results of the implant testing procedure can be properly evaluated.
- B.** Permanent sacral nerve stimulator implantation is considered medically necessary for the treatment of non-obstructive urinary retention when **all** of the criteria above (IIA1,2 &3) are met **and** a test stimulation of the device has provided at least a 50% decrease in residual urine volume as determined by ultrasound.
- C.** A current member-maintained intake, output, and symptoms **voiding diary** is required to be submitted with the Screening Trial PAR.

III. Treatment for Chronic Fecal Incontinence:

A. Prior to permanent sacral nerve stimulator implantation, a **screening trial** of sacral nerve stimulation over a period of up to 14 days is considered medically necessary for the treatment of chronic fecal incontinence when **all** of the following criteria are met:

1. Member has a structurally intact anal sphincter; **AND**
2. Member has experienced chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months; **AND**
3. Documentation of inadequate response to conservative treatment (e.g., biofeedback, dietary management, pharmacotherapy, strengthening exercises).
4. Member is able to demonstrate adequate ability to record **incontinence diary** data such that clinical results of the implant testing procedure can be properly evaluated.

B. Permanent sacral nerve stimulator implantation is considered medically necessary for the treatment of chronic fecal incontinence when **all** of the criteria above (III A1,2,3&4) are met **and** the test stimulation of the device, over a period of up to 14 days, has provided at least a 50% decrease in symptoms. Improvement is measured through **incontinence diaries**.

C. A current member-maintained **incontinence diary** is required to be submitted with the Screening Trial PAR **and** it is required to submit another member-maintained **incontinence diary** completed during the trial (3-4 days) with the Permanent SNS implantation PAR to evaluate the effectiveness of the trial.

D. Sacral nerve stimulation for fecal incontinence is contraindicated if **either** of the of the following apply:

1. The condition is related to anorectal malformation or defects of the anal sphincter over 60 degrees, visible sequelae of pelvic radiation such as active anal abscess(es) or anal fistula(s), or chronic inflammatory disease; **OR**
2. Fecal incontinence is related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Removal and replacement of the Sacral Nerve Stimulator is considered medically necessary when the following criteria are met:

1. If the device malfunctions, breaks, or becomes infected; **AND**
2. If the medical necessity criteria continue to be met; **AND**
3. If replacement is not part of the manufacturer warranty.

Additional Information

Sacral nerve stimulation is not covered in the following situations:

- Pregnancy;
- Pediatric use (under age 18);
- Patients with progressive, systemic neurological diseases

Bilateral Sacral Nerve Stimulation Implantation will not be covered. Per literature from Medtronic, the safety and effectiveness for bilateral stimulation has not been established.

Sacral nerve stimulation is considered investigational and not medically necessary for all other indications because the effectiveness for indications other than the ones listed above has not been established.

References

1. Oklahoma Health Care Authority; Policies & Rules, **OAC 317:30-3-1; 317:30-5-8.**
2. CMS, National Coverage Determination for Sacral Nerve Stimulation for Urinary Incontinence (230.18), 1/1/2002.
3. Novitas, Local Coverage Determination (LCD): Sacral Nerve Stimulation (L34707), Oklahoma, 10/9/2014. (Retired 09/20/2015)
4. BlueCross BlueShield of North Carolina: Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction, May 2000.
5. Aetna Clinical Policy Bulletin: Urinary Incontinence Treatments, Number 0223, 04/16/2021.
6. Aetna Clinical Policy Bulletin: Fecal Incontinence Treatments, Number 0611, 11/27/2020.
7. Medtronic. (2020). *Interstim Without Limits*. Retrieved from <https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/urology/sacral-neuromodulation.html>
8. Medtronic. (2021). *Reimbursement and Coding Sacral neuromodulation dx and proc code*. Retrieved from <https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/urology/sacral-neuromodulation/resources-support/reimbursement-coding.html>
9. Medtronic. (2021). *InterStim System Implant Procedure*. Retrieved from <https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/urology/sacral-neuromodulation/education-training/implant-procedure.html>