

02-61000-23

Original Effective Date: 01/01/01

Reviewed: 06/27/24

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## Subject: Sacral Nerve Neuromodulation/Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

<a href="#">Position Statement</a>	<a href="#">Billing/Coding</a>	<a href="#">Reimbursement</a>	<a href="#">Program Exceptions</a>	<a href="#">Definitions</a>	<a href="#">Related Guidelines</a>
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### DESCRIPTION:

Treatment using sacral nerve neuromodulation, also known as indirect sacral nerve stimulation, is one of several alternative modalities for patients 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 sacral nerve neuromodulation device consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet, kept by the patient, is used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

**Summary and Analysis of Evidence:** Sacral nerve neuromodulation for patients with urinary incontinence who failed conservative treatment, the evidence includes randomized controlled trials (RCTs) and case series. Results from the RCTs and case series with long-term follow-up have suggested that sacral nerve neuromodulation reduces symptoms of urge incontinence, urgency-frequency syndrome, nonobstructive urinary retention, and overactive bladder in selected patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Sacral nerve neuromodulation for patients with fecal incontinence who failed conservative treatment, the evidence includes RCTs, systematic reviews, and observational studies including several with long-term follow-up. Although relatively small, the available trials demonstrated improvements in incontinence relative to alternatives in selected patients. The evidence is insufficient to determine the effects of the technology on health outcomes. Patients with constipation who failed conservative treatment and receive sacral nerve neuromodulation, the evidence includes RCTs, systematic reviews, and case series including several with long-term follow-up. The available trials have not consistently

reported improvements in outcomes with sacral nerve neuromodulation. 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. An UpToDate article titled, Myofascial Pelvic Pain Syndrome in Females:Treatment (2024) includes, “Sacral neuromodulation (SNM), an implantable electrical stimulation device developed for the treatment of urinary urgency and frequency, has been used to treat multiple types of pelvic pain as well as refractory painful bladder syndrome/interstitial cystitis. However, studies of SNM for the treatment of MPPS [myofascial pelvic pain syndrome] are lacking. As sacral neuromodulation is an invasive procedure, we only use it for the subpopulation of women with painful bladder syndrome or refractory overactive bladder. In our experience, neuromodulation for urinary urgency and frequency in the setting of myofascial pain is sometimes effective to relieve pain but not enough to warrant its use in the absence of frequency and urgency”. The evidence for patients with chronic pelvic pain treated with sacral nerve neuromodulation is limited to systematic reviews of case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **POSITION STATEMENT:**

### **Urinary Incontinence and Non-Obstructive Urinary Retention**

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead **meets the definition of medical necessity** in members who meet **ALL** of the following criteria:

1. There is a diagnosis of at least **ONE** of the following:
  - a. Urge incontinence
  - b. Urgency-frequency syndrome
  - c. Non-obstructive urinary retention
  - d. Overactive bladder.
2. There is documented failure or intolerance to at least two 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).
3. Incontinence is not related to a neurologic condition **AND**
4. The member is an appropriate surgical candidate.

Permanent implantation of a sacral nerve neuromodulation device **meets the definition of medical necessity** in members who meet **ALL** of the following criteria:

1. **ALL** of the criteria listed above (1-4) are met **AND**
2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Other urinary/voiding applications of sacral nerve neuromodulation are considered **experimental or 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). The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Fecal Incontinence**

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead **meets the definition of medical necessity** in members who meet **ALL** of the following criteria:

1. 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.
2. 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.
3. 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.
4. The member has not had rectal surgery in the previous 12 months, or in the case of cancer, the member has not had rectal surgery in the past 24 months.
5. Incontinence is not related to a neurologic condition **AND**
6. The member is an appropriate surgical candidate.

Permanent implantation of a sacral nerve neuromodulation device **meets the definition of medical necessity** in members who meet **ALL** of the following criteria:

1. All of the criteria listed above (1-6) above are met **AND**
2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Sacral nerve neuromodulation is considered **experimental or investigational** in the treatment of chronic constipation or chronic pelvic pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Revision/Replacement**

Revision or replacement of an implanted sacral nerve stimulator **meets the definition of medical necessity** when all of the criteria above for urinary incontinence or fecal incontinence are met, the device is not functioning, and is no longer under warranty or cannot be repaired.

## **BILLING/CODING INFORMATION:**

### **CPT Coding**

64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
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64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrodes
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters

0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters
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### HCPCS Coding

A4290	Sacral nerve stimulator test lead, each
E0745	Neuromuscular stimulator, electronic shock unit
L8679	Implantable neurostimulator pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
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, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

### ICD-10 Diagnosis Codes That Support Medical Necessity:

N39.41	Urge incontinence
R15.0-R15.9	Fecal incontinence
R33.0-R33.9	Retention of urine
R35.0	Frequency of micturition
R35.81	Nocturnal polyuria
R35.89	Other polyuria

### LOINC Codes

The following information may be required documentation to support medical necessity: Physician history and physical, treatment plan, treatment notes including documentation of symptoms, behavior or pharmacologic interventions, and prior test stimulation (if applicable).

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note/treatment notes including documentation of symptoms	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Current, Discharge, or Administered Medications (i.e., pharmacologic interventions)	34483-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Neuromuscular electrophysiology studies (i.e. electronic analysis of implanted neurostimulator pulse generator system)	27897-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

**REIMBURSEMENT INFORMATION:**

Refer to sections entitled [POSITION STATEMENT](#).

**PROGRAM EXCEPTIONS:**

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage Products:**

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Sacral Nerve Stimulation for Urinary Incontinence (230.18) located at [cms.gov](https://www.cms.gov).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#)

## DEFINITIONS:

None applicable.

## RELATED GUIDELINES:

[Pelvic Floor Stimulation as a Treatment of Incontinence, 01-97000-06](#)

[Percutaneous and Subcutaneous Tibial Nerve Stimulation, 02-64000-01](#)

## OTHER:

None applicable.

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### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/27/24.

### GUIDELINE UPDATE INFORMATION:

01/01/01	New Medical Coverage Guideline.
01/01/02	Annual HCPCS coding update.
07/25/02	Reviewed.
08/15/03	Reviewed; no changes in coverage statement MCG changed to Active but no longer scheduled for routine review.
01/01/05	Annual HCPCS coding update: consisting of the revision of 64590, 95970, 95971, 95972 and 95973.
01/01/06	Annual HCPCS coding update: consisting of the deletion of E0752, E0754, E0756 and E0759 and the addition of L8680, L8681, L8682, L8683 and L8684.
01/01/07	Annual HCPCS coding update: consisting of the revision of 64590 and 64595.
09/15/07	Review and revision of guideline consisting of updated references and reformatted guideline.
09/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: revised descriptor for code L8681.
07/15/09	Annual review: position statements maintained, coding and references updated.
06/15/10	Annual review: position statements maintained and references updated.
10/15/10	Revision: formatting changes and related ICD-10 codes added.
08/15/11	Revision; formatting changes.
10/01/11	Revision; formatting changes.
01/01/12	Annual HCPCS update. Revised descriptor for codes 64561, 64581, & 95970-95973.
05/15/12	Annual review; title, position statements, coding/billing section, and references updated; formatting changes.
10/15/12	Permanent implantation criteria updated; formatting changes.
01/01/13	Annual HCPCS update. Revised descriptor for code 64561.

06/15/13	Annual review; position statement section and references updated; formatting changes.
01/01/14	Annual HCPCS update. Added code L8679.
06/15/14	Annual review; Update position statements, coding, and references; formatting changes.
01/01/15	Annual HCPCS/CPT update. Revised code 95972.
10/15/15	Annual review; position statements, coding, & references updated; formatting changes.
01/01/16	Annual HCPCS/CPT update; code 95972 revised, code 95973 deleted.
01/01/17	Annual CPT/HCPCS update. Revised 95972; formatting changes.
04/15/17	Revision; position statements maintained, description section and references updated.
07/15/18	Review; description, position statements, coding, and references updated.
01/01/19	Annual CPT/HCPCS coding update. Revised codes 95970-95972.
07/15/20	Review; position statements maintained and references updated.
01/01/22	Annual CPT/HCPCS coding update. Code 64581 revised.
06/15/22	Review: Position statements maintained; coding and references updated.
05/25/23	Update to Program Exceptions section.
01/01/24	Position statements maintained. Annual CPT/HCPCS coding update. Codes 0786T- 0789T added; codes 64590, 64595 revised.
07/15/24	Review: Revision/replacement position statement added; description and references updated.