02-61000-23

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Reviewed: 05/26/22

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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.

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.

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.

BILLING/CODING INFORMATION:

CPT Coding

64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of implanted peripheral or gastric neurostimulator pulse generator or receiver
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

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	18733-6	18805-2	Include all data of the selected type that represents observations made six months or

including documentation of symptoms			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.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, 01-97000-06
Percutaneous 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 05/26/22.

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.