02-61000-23

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Reviewed: 06/28/18

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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:

Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes. Urgency-frequency is a prominent symptom of interstitial cystitis. Urinary retention is the inability to completely empty the bladder of urine completely. Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

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 (eg, 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 is kept by the patient and can be 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	Incision for 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

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.

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Sacral Neuromodulation (L36296) located at fcso.com.

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.

REFERENCES:

1. Abrams P, Blaivas JG, Fowler CJ, The Role of Neuromodulation in the Management of Urinary Urge Incontinence, BJU International, Vol 91, Issue 4, Pages 355-359, July 2009.
2. Altomare DF, Ratto C, Ganio E, et al, Long-Term Outcomes of Sacral Nerve Stimulation for Fecal Incontinence, Dis Colon Rectum, 2009 January; 52(1): 11-7.
3. American Urological Association (AUA) Guideline. Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome, 2011, accessed at auanet.org.
4. American Urological Association (AUA). Guideline on Diagnosis and Treatment of Overactive Bladder, 2014; accessed at auanet.org.
5. American Urological Association (AUA). Position Statement Regarding Sacral Nerve Stimulation for Urinary Incontinence. October 18, 2000, accessed at auanet.org.
6. Blue Cross Blue Shield Association Medical Policy Reference Manual, 7.01.69 Sacral Nerve Neuromodulation/Stimulation, 04/18.
7. Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Sacral Nerve Stimulation Urge Incontinence. TEC Assessments 1998, Tab 18.
8. Blue Cross Blue Shield Association. Technology Evaluation Center (TEC). Sacral Nerve Stimulation Urinary Urgency/Frequency. TEC Assessments 2000, Tab 7.
9. Centers for Medicare & Medicaid Services (CMS), NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18), accessed at cms.gov.

10. El-Gazzaz G, Zutshi M, et al, Sacral Neuromodulation for the Treatment of Fecal Incontinence and Urinary Incontinence in Female Patients: Long-Term Follow-up, International Journal of Colorectal Disease, Vol 24, Number 12, December 2009.
11. First Coast Service Options, Inc. (FCSO), LCD Sacral Neuromodulation (L36296), accessed at fcso.com.
12. Groenendijk PM, et al, Urodynamic Evaluation of Sacral Neuromodulation for Urge Urinary Incontinence, BJU Int. 2008 February; 101(3): 325-9.
13. Herbison GP, Arnold EP, Sacral Neuromodulation with Implanted Devices for Urinary Storage and Voiding Dysfunction in Adults, National Institutes of Health, April 15, 2009.
14. Kenefick NJ. Sacral nerve neuromodulation for the treatment of lower bowel motility disorders. Ann R Coll Surg Engl. 2006 Nov; 88(7): 617-23.
15. Leroi AM, Parc Y, Lehur PA, Mion F, Barth X, Rullier E, Bresler L, Portier G, Michot F; Study Group. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. Ann Surg. 2005 Nov; 242(5): 662-9.
16. Mowatt G, Glazener C, Jarrett M. Sacral nerve stimulation for faecal incontinence and constipation in adults. Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD004464. DOI: 10.1002/14651858.CD004464.pub2.
17. National Collaborating Centre for Women's and Children's Health, Urinary Incontinence: The Management of Urinary Incontinence in Women, London (UK), Royal College of Obstetricians and Gynaecologists (RCOG), October 2006, accessed at guideline.gov. 04/16/10.
18. National Guideline Clearinghouse (NGC). Guideline summary NGC-5720 Chronic Pelvic Pain; Agency for Healthcare Research and Quality (AHRQ); accessed at guideline.gov 04/22/13.
19. National Institute for Clinical Excellence (NICE), Faecal Incontinence (QS54) Quality Standards, Issued February 2014. Accessed at nice.org 08/26/15.
20. National Institute for Clinical Excellence (NICE). Faecal Incontinence: The Management of Faecal Incontinence in Adults; NICE Clinical Guideline 49. 2007; accessed at nice.org.uk 04/22/13.
21. Oerlemans, D, Van Kerrebroeck P, Sacral Nerve Stimulation for Neuromodulation of the Lower Urinary Tract, Neurourology and Urodynamics, Vol 27 Issue 1, pages 28-33, 2008.
22. Pilkington SA, Emmett C, Knowles CH, et al. Surgery for constipation: systematic review and practice recommendations: Results V: Sacral Nerve Stimulation. Colorectal Dis. Sep 2017;19(Suppl 3):92-100.
23. Rao SS, American College of Gastroenterology Practice Guidelines-Diagnosis and Management of Fecal Incontinence, 2004; accessed at s3.gi.org/physicians/guidelines/FecalIncontinence.pdf 08/26/15.
24. Roth TJ, Vandersteen DR, Hollatz P, Sacral Neuromodulation for the Dysfunctional Elimination Syndrome: A Single Center Experience with 20 Children, The Journal of Urology, Vol 180, Issue 1, pages 306-311, July 2008.
25. Satish SC, Practice Guidelines- Diagnosis and Management of Fecal Incontinence, American Journal of Gastroenterology, 2004, 1585-1604.
26. Tjandra JJ, et al, Practice Parameters for the Treatment of Fecal Incontinence, Dis colon Rectum 2007; 50: 1497-1507, accessed at fascrs.org 04/23/14.
27. White, WM, Dobmeyer-Dittrich C, Klein FA, Wallace LS, Sacral Nerve Stimulation for Treatment of Refractory Urinary Retention: Long-Term Efficacy and Durability, Urology, Vol 71, Issue 1, Pages 71-74, January 2008.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the BCBSF Medical Policy & Coverage Committee on 06/28/18.

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.