Anthem

Clinical UM Guideline

Subject: Sacral Nerve Stimulation as a Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury
Guideline #: CG-SURG-08 **Publish Date:** 06/28/2023
Status: Reviewed **Last Review Date:** 05/11/2023

Description

This document addresses sacral nerve stimulation as a treatment of neurogenic bladder due to spinal cord injury. The device consists of extradural electrodes that are attached to the sacral anterior nerve roots, a subcutaneously implanted receiver-stimulator, and an external battery-powered controller and transmitter. The system is self-activated and provides low levels of electrical stimulation designed to produce functional contraction of the innervated muscles. Implantation is frequently performed in conjunction with a posterior rhizotomy to eliminate reflex incontinence.

Note: Please see the following related documents for additional information:

- SURG.00010 Treatments for Urinary Incontinence
- CG-SURG-95 Sacral Nerve Stimulation and Percutaneous or Implantable Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention

Clinical Indications

Medically Necessary:

Self-activated electrical stimulation of intact anterior sacral nerve roots using an implantable device (for example, Vocare Bladder System/FineTech Brindley Bladder Control System) to provide urination on demand and reduce post-void residual volume is considered **medically necessary** for individuals who meet all of the following criteria:

- Have a neurogenic bladder due to a clinically complete* suprasacral spinal cord lesion;**and**
- Have intact parasympathetic innervation of the bladder;**and**
- Are skeletally mature and neurologically stable;**and**
- Cannot be adequately managed with intermittent or condom catheterization.

Not Medically Necessary:

Self-activated electrical stimulation of the anterior sacral roots is considered **not medically necessary** for all other indications.

*As defined by the American Spinal Injury Association (ASIA) Impairment Scale.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met for sacral root neurostimulators:

CPT	
63185	Laminectomy with rhizotomy, 1 or 2 segments
63190	Laminectomy with rhizotomy; more than 2 segments
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural [when specified as sacral root neurostimulator]
HCPCS	
L8680	Implantable neurostimulator electrode, each [when specified as sacral root neurostimulator]
L8682	Implantable neurostimulator radiofrequency receiver [when specified as sacral root neurostimulator]
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
ICD-10 Procedure	
018R0ZZ	Division of sacral nerve, open approach
018R3ZZ	Division of sacral nerve, percutaneous approach
018R4ZZ	Division of sacral nerve, percutaneous endoscopic approach
00HU0MZ	Insertion of neurostimulator lead into spinal canal, open approach
00HU3MZ	Insertion of neurostimulator lead into spinal canal, percutaneous approach
00HU4MZ	Insertion of neurostimulator lead into spinal canal, percutaneous endoscopic approach
00HV0MZ	Insertion of neurostimulator lead into spinal cord, open approach
00HV3MZ	Insertion of neurostimulator lead into spinal cord, percutaneous approach
00HV4MZ	Insertion of neurostimulator lead into spinal cord, percutaneous endoscopic approach
ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above for sacral nerve root stimulators when criteria are not met and for all other indications.

Discussion/General Information

Spinal cord injury (SCI) can result in varying degrees of neurological impairment depending on the location and severity of the injury. The American Spinal Injury Association (ASIA) Impairment Scale is a system used to classify or describe the extent of spinal cord injuries. The classification is as follows:

A = Complete: No motor and sensory function is preserved in the sacral segments S4-S5.
B = Incomplete: Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5.
C = Incomplete: Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3.
D = Incomplete: Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more.
E = Normal: Motor and sensory function are normal.

Supra-sacral spinal cord injury may result in neurogenic bladder, characterized in part by frequent urinary tract infections from inadequate bladder emptying. The high bladder pressures related to large post-void residuals can lead to autonomic dysreflexia, vesicoureteral reflux, upper urinary tract dilations, hydronephrosis, and eventual renal failure.

Sacral anterior root stimulation is intended to provide bladder evacuation by delivering electrical stimulation to intact spinal nerve roots in order to produce functional contraction of the innervated muscles. Implantation of a sacral anterior root stimulator is typically performed in conjunction with a simultaneous posterior rhizotomy. The rhizotomy results in an areflexive bladder with low intravesicular pressure and high compliance. When the user activates the implanted stimulator, the urethral sphincter and bladder contract and relax, allowing the bladder to empty on demand with low residual urine volumes.

The Vocare Bladder System (Finetech Medical, Hertfordshire, UK) has received approval by the Food and Drug Administration (FDA) for stimulation of the sacral anterior nerve root. Outside of the United States, the device is known as the Finetech-Brindley device. The FDA-labeled indication, approved in 1999, included the following:

> The Neurocontrol Vocare Bladder System is indicated for the treatment of patients who have clinically complete spinal cord lesions with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce post-void residual volumes of urine.

Intact parasympathetic innervation of the bladder is described by the manufacturer as having “intact reflex bladder contractions” (Finetech Medical, 2021). The Vocare package insert further specifies:

> Prior to implant, patients should show reflex bladder contraction with an increase in detrusor pressures over baseline of at least 35 cm H20 in women and 50 cm H20 in men during cystometry. This ensures that parasympathetic preganglionic neurons from the conus medullaris to the bladder are intact.

The Vocare Bladder System consists of the following implantable external and surgical components.

- Implanted components consist of the implantable receiver-stimulator, which is implanted subcutaneously. The receiver-stimulator is attached to extradural electrodes that are attached to the sacral anterior nerve roots.
- External components consist principally of an external, battery-powered controller and transmitter. The external controller generates and delivers a sequence of electrical pulses that are emitted as electromagnetic fields from the transmitter. The transmitter is placed on the skin over the subcutaneously implanted receiver-stimulator.
- The surgical components include a variety of surgical tools to assist in the identification of the appropriate nerve roots for posterior rhizotomy and the optimal placement of the implanted extradural electrodes.
- Posterior rhizotomy requires a S1-S3 laminectomy. The extradural electrodes are implanted during the same procedure.

The Vocare Bladder System received FDA approval through a Humanitarian Device Exemption and as such, randomized controlled trials (RCTs) were not required for approval. The FDA approval was based on the Creasey (2001) prospective trial. The study included 23 individuals with complete suprasacral spinal cord injuries who underwent implantation of the device in association with posterior rhizotomy and were followed for a minimum of 3 months. Comparisons were made with the device turned on and off; thus subjects served as their own controls. There was a significant improvement in bladder emptying, as measured by voided volumes and post void residual, when the device was turned on compared with the off condition. For example, at 3 months, 19 of 21 individuals (91%) for whom data were available voided more than 200 mL of urine on demand with the device turned on versus no participants voiding more than 200 mL of urine with the device turned off. Diary data at 12 months were available for 17 participants; of these, 12 reported a reduction in urinary incontinence.

Ren and colleagues (2015) performed a literature review of electrical nerve stimulation used for promotion of micturition in individuals with spinal cord injuries. There were no RCTs or other controlled trials found. The authors identified 14 uncontrolled studies using Brindley devices published between 1982 and 2013. Continence rates ranged from 59% to 93%. Review authors did not pool study findings. However, they concluded that “electrical nerve stimulation, mainly conducted with the Finetech-Brindley stimulator, is a considerable option for bladder management in SCI patients.” As noted above, the Finetech-Brindley device is branded as Vocare in the United States.

References

Peer Reviewed Publications:

1. Creasey GH, Grill JH, Korsten M, et al. Implanted Neuroprosthesis Research Group. An implantable neuroprosthesis for restoring bladder and bowel control to patients with spinal cord injuries: a multicenter trial. Arch Phys Med Rehabil. 2001; 82(11):1512-1519.
2. Ren J, Chew DJ, Biers S, Thiruchelvam N. Electrical nerve stimulation to promote micturition in spinal cord injury patients: A review of current attempts. Neurourol Urodyn. 2016; 35(3):365-370.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Spinal Injury Association. ASIA Impairment Scale. Available at:https://asia-spinalinjury.org/wp-content/uploads/2019/10/ASIA-ISCOS-Worksheet_10.2019_PRINT-Page-1-2.pdf. Accessed on March 8, 2023.
2. Finetech Medical. Finetech-Brindley – Bladder Control System. 2021. Available at:https://finetech-medical.co.uk/products/finetech-brindley-bladder-control-system/. Accessed on March 8, 2023.
3. NeuroControl Corporation VOCARE Bladder System Implantable Functional Neuromuscular Stimulator package insert. 1999. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf/H980008C.pdf. Accessed on March 8, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Description, Discussion/General Information and References sections updated.
Reviewed	05/12/2022	MPTAC review. References section updated.
Reviewed	05/13/2021	MPTAC review. Discussion/General Information and References sections updated. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. References sections updated.
Reviewed	06/06/2019	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Description, Discussion and Reference sections updated.
Revised	08/03/2017	MPTAC review. In the Clinical Indication section, changed “(American Spinal Injury Association)” to “*”. Added “*As defined by the American Spinal Injury Association (ASIA) Impairment Scale” to the bottom of the Clinical Indication section. Updated Discussion and References sections.
Reviewed	08/04/2016	MPTAC review. References and Websites updated. Removed ICD-9 codes from Coding section. Updated formatting in Clinical Indications section.
Reviewed	08/06/2015	MPTAC review. Discussion and Reference sections updated.
Reviewed	08/14/2014	MPTAC review. Description, Discussion and References sections updated.
Reviewed	08/08/2013	MPTAC review. References section updated.
Reviewed	08/09/2012	MPTAC review. Description and References sections updated.
Reviewed	08/18/2011	MPTAC review. Coding, Discussion and References sections updated.
Reviewed	08/19/2010	MPTAC review. Discussion, Coding and References links updated.
Reviewed	08/27/2009	MPTAC review. Note below Description, Discussion and References updated.
Reviewed	08/28/2008	MPTAC review. Medically Necessary statement and Not Medically Necessary statement clarified. No change to stance. Description, Discussion and References updated.
Revised	08/23/2007	MPTAC review. Medically Necessary statement clarified. Added Not Medically Necessary statement. References and Coding updated.
Reviewed	09/14/2006	MPTAC review. Updated References and Coding.
	11/22/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Guideline Number	Title
Anthem, Inc.			No document
Anthem BCBS	07/08/2002	Anthem SE Memo1118	Stimulation of the Sacral Anterior Root Combined with Posterior Sacral Rhizotomy in Patients with Spinal Cord Injury
WellPoint Health Networks, Inc.	06/24/2004	2.08.10	Sacral Nerve Stimulation as a Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury

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