



BlueCross BlueShield  
of Alabama

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**Name of Policy:**

**Stimulation of the Sacral Anterior Root Combined with Posterior Sacral Rhizotomy in Patients with Spinal Cord Injury**

Policy #: 160  
Category: Surgery

Latest Review Date: May 2010  
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

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**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

### **Description of Procedure or Service:**

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

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

- Implanted components consist of the implantable receiver-stimulator, which is implanted subcutaneous. 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 an S1-S3 laminectomy. The extradural electrodes are implanted during the same procedure.

### **Policy:**

**Stimulation of the sacral anterior root** using an implantable device in conjunction with a posterior rhizotomy **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for patients with a suprasacral complete spinal cord lesion and an associated neurogenic bladder.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

### **Key Points:**

The VOCARE Bladder System received FDA approval through a humanitarian device exemption; therefore, randomized clinical studies were not required for approval. The FDA approval was based on a trial of 23 patients who underwent implantation of the device in association with posterior rhizotomy and were followed for a minimum of 3 months. The device was turned on and off for comparisons to be made. Thus, patients served as their own controls. There was noted to be significant improvement in bladder emptying as measured by the voided volumes and post-void residual.

Implantation stimulation of sacral anterior nerve root in association with posterior rhizotomy has been widely used in Europe for several decades. Case series of over 500 patients had been reported with favorable results. The results reported from the clinical trial used for FDA approval were consistent with those that were later reported in larger case series. For example, Van Kerrebroeck and colleagues reported on the outcomes of 47 patients who were followed up for a minimum of 6 months. Complete continence was reported in 43 of the 47 patients, and 41 of the 47 patients used only the stimulator for bladder emptying. The residual urine volume also decreased to less than 50 mL in 41 patients. The incidence of urinary tract infections also decreased. Another study published by Egon and colleagues reported on a case series of 93 patients. A total of 83 of the 93 patients used their implants for micturition with residual volumes less than 50 mL.

#### **May 2008 Update**

There was no new published peer-reviewed literature identified that would alter the coverage statement of this policy.

#### **May 2010 Update**

The National Guideline Clearinghouse has developed a guideline for bladder management for adults with spinal cord injury. These guidelines were developed in 2006 with updates periodically since that time. The following categories are listed in the guideline:

- Intermittent Catheterization-recommended for those most likely able to perform and have sufficient hand skills or a willing caregiver and those who should avoid this method of bladder management
- Crede' and Valsalva-for individuals with lower motor neuron injuries with low outlet resistance or who have had a sphincterotomy and in those individuals to avoid this method
- Indwelling Catheterization- recommended for those with poor hand skills, high fluid intake, cognitive impairment or active substance abuse, elevated detrusor pressures managed with anticholinergic medications or other means; may consider suprapubic catheterization, long-term complications
- Reflex Voiding-recommended for use in males with post-spinal shock with adequate bladder contractions and have hand skills to put on a condom catheter, empty leg bag or willing caregiver, poor compliance with fluid restriction, small bladder capacity, small post-void residual volumes, ability to maintain a condom catheter in place; those not to consider reflex voiding, complications, surgical methods
- Alpha-Blockers- these medications may be considered for use on their own or as a supplement to other forms of treatment
- Botulinum Toxin Injection- injected into the sphincter to help improve voiding with detrusor sphincter dyssynergia
- Endourethral Stents- consider for those with detrusor sphincter dyssynergia in individuals who want to reflex void and have sufficient hand skills or willing caregiver for intermittent catheterization, history of repeated history of autonomic dysreflexia, etc.; complications.

- Transurethral Sphincterotomy-consider TURS for those who want to use reflex voiding and who have sufficient hand skills or willing caregiver, history of autonomic dysreflexia with a noncompliant bladder, experience difficult catheterization due to false passages, inadequate bladder drainage with severe bladder wall changes, drop in renal function and stone disease, post-ejaculatory reflux with the potential for repeated epididymo-orchitis, experience failure with or intolerance to anticholinergic medication for intermittent catheterization, experience failure with or intolerance to alpha-blockers with reflex voiding
- Electrical Stimulation and Posterior Sacral Rhizotomy- consider in those with high post-void residual volumes, chronic or recurrent urinary tract infection, problems with catheters, reflex incontinence, reduced bladder capacity and compliance, caused by detrusor hyperreflexia, intolerance of anticholinergic medication, detrusor sphincter dyssynergia, and autonomic dysreflexia
- Bladder Augmentation- in those with intractable involuntary bladder contractions causing incontinence, can perform intermittent catheterization, desire to convert from reflex voiding to an intermittent catheterization program, has high risk for upper tract deterioration
- Continent Urinary Diversion- for those in whom it is not feasible to augment the bladder, for those who are unable to access their native urethra, females with tetraplegia, males with unsalvageable bladders secondary to urethral fistula and sacral pressure ulcers, bladder cancer requiring cystectomy
- Urinary Diversion- for those with lower urinary complications secondary to indwelling catheters, urethrocuteaneous fistulas, perineal pressure ulcers, urethral destruction in females, hydronephrosis secondary to a thickened bladder wall or to vesicoureteral reflux or failed reimplant, bladder cancer requiring cystectomy
- Cutaneous Ileovesicostomy- for those who require urinary diversion with normal ureterovesical junction, secondary procedures may be needed

### **Key Words:**

Stimulation of the sacral anterior root, posterior sacral rhizotomy, spinal cord injury, VOCARE Bladder System, neurogenic bladder

### **Approved by Governing Bodies:**

The VOCARE Bladder System received FDA approval on the humanitarian device exemption in 1999.

### **Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan.

Pre-certification/Pre-determination requirements: Not applicable

**Current Coding:**

CPT:	<b>63190</b>	Laminectomy with rhizotomy; more than two segments
	<b>63655</b>	Laminectomy for implantation of neurostimulator electrodes
	<b>63685</b>	Incision and subcutaneous or spinal neurostimulator pulse generator or receiver

In addition, there are a large number of pre- and post- work-up procedures to assess the urodynamics. These would include the following procedures:

<b>51600</b>	Injection procedure for cystography or voiding urethrocytography
<b>51726</b>	Complex cystometrography
<b>51741</b>	Complex uroflowmetry
<b>51797</b>	Voiding studies, intra-abdominal voiding pressure
<b>74420</b>	Urography, retrograde
<b>74430</b>	Cystography

These procedures may be done both pre- and postoperatively as an assessment of urodynamics.

**Effective for dates of service on or after January 1, 2005:**

<b>63685</b>	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
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**Effective for dates of service on or after January 1, 2008:**

<b>51797</b>	Voiding pressure studies (vp); intra-abdominal voiding pressure (ap) (rectal, gastric, intraperitoneal) (list separately in addition to code for primary procedure)
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**References:**

1. Brindley, GS. *The first 500 patients with sacral anterior root stimulator implants: General description*, Paraplegia, 1994; 32(12): 795-805.
2. Creasey, GH. *Electrical stimulation of sacral roots for micturition after spinal cord injury*, Urol Clin North Am, 1993; 20(3): 505-15.
3. Creasey GH, Dahlberg, JE. *Economic consequences of an implanted neuroprosthesis for bladder and bowel management*, Arch Phys Med Rehabil, 2001; 82(11): 1520-5.
4. Creasey GH, Grill JH, Korsten M, et al. *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): 1512-19.
5. Egon G, Barat M, Columbel P, et al. *Implantation of anterior sacral root stimulators combined with posterior sacral rhizotomy in spinal injury patients*, Worl J Urol, 1998; 16(5): 342-49.
6. FDA Web site: <http://www.fda.gov>.
7. National Guideline Clearinghouse. *Bladder management for adults with spinal cord injury: A clinical practice guideline for health-care providers*. <http://www.guideline.gov>.

8. Van Kerrebroeck PE, Koldewijn EL, Rosier PF, et al. *Results of the treatment of neurogenic bladder dysfunction in spinal cord injury by sacral posterior root rhizotomy and anterior sacral root stimulation*, J Urol, 1996; 155(4): 1378-81.

### **Policy History:**

Medical Policy Group, May 2004 (3)

Medical Policy Administration Committee, May 2004

Available for comment June 28-August 11, 2004

Medical Policy Group, May 2006 (1)

Medical Policy Group, May 2008 (1)

Medical Policy Group, May 2010 (1) Key Points updated, no policy change

Medical Policy Group, September 2012 (3): **Active Policy but no longer scheduled for regular literature reviews and updates.**

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*