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

Medical Policy

Section
Surgery

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Description

Suprasacral spinal cord injury may result in neurogenic bladders, 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. (Autonomic dysreflexia is a clinical phenomenon affecting patients with a spinal cord injury above the sympathetic outflow at T5-T6. Any noxious stimulus arising below this level may irritate reflex sympathetic activity, which may result in life-threatening hypertension.) Bladder management after spinal cord injury typically attempts to increase bladder capacity, maintain low pressure storage of urine, minimize risk of urinary tract infection by limiting post-void residual urine, and prevent incontinence. Conservative treatment of neurogenic bladder includes use of anticholinergic drugs to control reflex incontinence and autonomic hyperreflexia, and intermittent or permanent catheterization for bladder emptying. External sphincterotomy or urinary diversion is a surgical option.

Electrical stimulation to improve bladder control has been investigated since 1954, with stimulation of the sacral anterior (i.e., motor) nerve roots first attempted in 1978. Sacral anterior root stimulation is intended to provide bladder evacuation by delivering electrical stimulation to intact spinal nerve roots to elicit functional contraction of the innervated muscles. (In contrast, the Interstim device, addressed in policy No. 7.01.69, is designed to modulate the neural reflexes and does not induce contraction.) 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 intravesical pressure and high compliance. These features limit reflex incontinence and autonomic hyperreflexia. When the patient activates the implanted stimulator, the urethral sphincter and bladder contract and relax, allowing the bladder to empty on demand with low residual urine volumes.

While sacral anterior root stimulation has been widely used in Europe for many years, in this country, only 1 implantable device, the Vocare Bladder System, has received approval by the
The use of 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 an S1-S3 laminectomy. The extradural electrodes are implanted during the same procedure.

Extensive pre- and postoperative urodynamic testing is an associated part of the overall procedure.

The Vocare Bladder System received FDA approval under a Humanitarian Device Exemption. This category of FDA approval is applicable to those devices intended to treat a population of less than 4,000 individuals. A Humanitarian Device Exemption does not require clinical data validating the effectiveness of the device, but rather only data validating its safety and an assessment that the probable benefit exceeds the risks.

**Note:** Stimulation of the sacral anterior motor nerve roots must be distinguished from stimulation of the sacral sensory nerve. Stimulation of the sacral sensory nerve, indicated as a treatment of incontinence and urinary retention in patients without spinal cord injury, is considered separately in policy No. 7.01.69.

**Policy**

Stimulation of the sacral anterior roots using an implantable device, in conjunction with a posterior rhizotomy, may be considered medically necessary for patients with a suprasacral complete spinal cord lesion and an associated neurogenic bladder.

**Note:** This policy does not address implantable electrical stimulation of sacral nerves (not nerve roots) as a treatment of urinary incontinence or retention in patients without spinal cord injury. This procedure is addressed separately in policy No. 7.01.69.
Policy Guidelines

The following series of CPT codes are used to describe the various components of the overall procedure.

Pre- and Postoperative Work-up

*51600: Injection procedure for cystography or voiding urothrocystography
*51726: Complex cystometrogram
*51741: Complex uroflometry
*51797: Voiding studies, intra-abdominal voiding pressure
*74430: Cystography
*74420 Urography, retrograde

*The above procedures may be done both pre- and postoperatively

72148 - 72149: MRI of the lumbar spinal canal, with or without contrast, respectively

Surgery

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

Rationale

Implantable stimulation of sacral anterior nerve roots in association with posterior rhizotomy has been widely used in Europe for several decades. Case series of over 500 patients have been reported. (1) The FDA approval of the Vocare Bladder System was based on a trial of 23 patients who underwent implantation of the device in association with posterior rhizotomy and were followed up for a minimum of 3 months. (2) Comparisons were made with the device turned either on or off; thus patients served as their own controls. The principal outcome measures were improvement in bladder emptying as evidenced by the ability to urinate more than 200 mL on demand with post-void residuals less than 50 mL. Secondary endpoints include reduction in the use of urinary catheters, number and severity of episodes of urinary incontinence, reduction in incidence of urinary tract infections, and results of a user satisfaction survey.

After 3 months, 90% of the patients were able to void greater than 200 mL on demand and 81% had a post-void residual less than 50 mL. A total of 73% of patients reported fewer urinary tract infections, and at 6 months, about one half of the patients were using the stimulator exclusively for micturition; no external devices, such as catheters, were needed.
The results reported in this small clinical trial are consistent with those reported in larger case series. (3) For example, Van Kerrebroeck and colleagues reported on the outcomes of 47 patients who were followed up for a minimum of 6 months. (4) 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. Egon and colleagues reported on a case series of 93 patients. (5) A total of 83 of the 93 patients used their implants for micturition with residual volumes less than 50 mL.

2002-3 Update

A search of the literature based on the MEDLINE database for the period of 2000 though July 2002 did not identify any published articles that would prompt a change in the policy statement. The study conducted as part of the FDA approval process has now been published in the peer-reviewed literature. (6) A small study of 12 patients has also suggested that use of a neuroprosthesis greatly reduces the cost of managing a neurogenic bladder. (7)

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