



**Subject:** *Sacral Nerve Stimulation for Urinary Incontinence*

**Number:** **200311-0005**

Effective date: 12/22/2003

Revision date(s): 07/2000, 11/21/2003

**Important note**

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. The Centers for Medicare and Medicaid's *Coverage Issues Manual* can be found on the following Web site: <http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

**Overview**

**Sacral nerve stimulation (SNS)** is an implantable, permanent device that modulates the neural pathways controlling bladder function. This is one of several methods used to treat urinary urge incontinence, significant symptoms of urgency-frequency or nonobstructive urinary retention, when other behavioral and/or pharmacologic therapies have failed.

Urge incontinence is the 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. Urinary retention is the inability to completely empty the bladder of urine.

As an implantable device, this item does not go towards the prosthetic/orthotics devices and durable medical equipment benefit limit.

**Policy and criteria**

**NOTE:** These services require prior authorization by the plan medical director.

**When services are covered:**

We cover **sacral nerve stimulation (SNS)** as treatment for urge incontinence, urgency-frequency, and nonobstructive urinary retention when ALL of the following criteria are met:

1. Patient has not responded to prior behavioral *and* pharmacologic interventions over six months of treatment; AND
2. Incontinence is not related to a neurologic condition; AND
3. Symptoms of incontinence have been present for at least 12 months *and* have resulted in significant disability, such as the limited ability to work or participate in activities outside of the home; AND
4. A test stimulation has demonstrated a 50% or greater improvement in incontinence, as documented in voiding diaries submitted for review with the request.

Behavioral interventions include pelvic floor exercises, biofeedback, timed voids and fluid management. Based on the reason for the incontinence, pharmacologic interventions can include two different

anticholinergic drugs *or* a combination of an anticholinergic and a tricyclic antidepressant *or* alpha blockers and cholinergics, with antibiotics used for urinary tract infections.

**Covered services:**

The following services related to medically necessary SNS are covered:

- evaluation with a plan affiliated urologist
- trial or test stimulation
- inpatient facility care and related professional services, including postsurgical follow-up care
- sacral nerve stimulator

**When services are not covered:**

We **do not cover** services when the above criteria are not met or any other applications of SNS **or for any procedures or devices not listed above.**

Any other applications for SNS have not been proven in the peer-reviewed literature and are considered investigational. These noncovered uses include, but may not be limited to:

- Stress incontinence or urge incontinence due to a neurologic condition, such as
  - detrusor hyperreflexia
  - multiple sclerosis
  - spinal cord injury
- Other types of chronic voiding dysfunction

**Codes:**

Codes	Number	Description
CPT	64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
	64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
	64585	Revision or removal of peripheral neurostimulator electrodes
	64590	Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling
	64595	Revision or removal of peripheral pulse generator or receiver
HCPCS	A4290	Sacral nerve stimulation test lead, each
	E0745	Neuromuscular stimulator, electronic shock unit
	E0752	Implantable neurostimulator electrode, each
	E0756	Implantable neurostimulator pulse generator
	E0759	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement

**FCHP products to which this policy applies:**

- ⊕ FCHP Direct and FCHP Select Care (HMO)
- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home
- ⊕ Medicare plan – *reminder* to refer to CMS for policy and criteria

**References**

1. Bosch J, Groen J. Sacral (S3) segmental nerve stimulation as a treatment for urge incontinence in patients with detrusor instability: Results of chronic electrical stimulation using an implantable neural prosthesis. J Urol. 1995;154:504-507.
2. Centers for Medicare & Medicaid Services. National Coverage Determination. Pub 6. Sacral Nerve Stimulation For Urinary Incontinence. January 1, 2002.
3. Hayes, Winifred S. Technology Report. Implantable Sacral Nerve Stimulation for Urinary Voiding Dysfunction. April 2003.
4. Janknegt RA, et al. Improving neuromodulation techniques for refractory voiding dysfunctions: Two-stage implant. Urology. 1997;49:358-362.
5. Jeyaseelan SM, Haslam EJ, Winstanly J et al. An evaluation of a new pattern of electrical stimulation as a treatment for urinary stress incontinence: a randomized, double-blind, controlled trial. Clin Rehabil 2000;14(6):631-40.
6. Schmidt RA, et al. Sacral nerve stimulation for the treatment of refractory urinary urge incontinence. J Urol. 1999;162(2):352-357.
7. Shaker HS, Hassouna M. Sacral nerve root neuromodulation: An effective treatment for refractory urge incontinence. J Urol. 1998;159:1516-1519.
8. Yamanishi, T, Yasuda K, Sakakibara R et al. Randomized, double-blind study of electrical stimulation for urinary incontinence due to detrusor overactivity. Urology 2000;55(3):353-7.

**Mandated benefit/Regulatory issues**

- Federal
- Commonwealth of Massachusetts
- Medicare – National Policy
- Medicare – Local Medical Review Policy
- Not applicable

**Committee review dates:**

**Technology Assessment Committee:** 07/2000  
**Utilization Management Committee:** 06/2003

Approved by: \_\_\_\_\_ Signature on file \_\_\_\_\_ 12/18/2003 \_\_\_\_\_  
 Dennis A. Batey, M.D. Vice President and Chief Medical Officer \_\_\_\_\_ Date