

# MEDICAL POLICY

<b>SUBJECT: SACRAL NERVE STIMULATION</b>	<b>EFFECTIVE DATE: 11/19/99</b> <b>REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14</b>
<b>POLICY NUMBER: 7.01.10</b> <b>CATEGORY: Technology Assessment</b>	<b>PAGE: 1 OF: 8</b>
<ul style="list-style-type: none"><li><i>If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.</i></li><li><i>Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.</i></li><li><i>Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.</i></li></ul>	

## **POLICY STATEMENT:**

- I. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has been medically proven to be effective and therefore, **medically appropriate** in patients with urge incontinence, urgency-frequency, and non-obstructive urinary retention that has not responded to conventional treatment (e.g., bladder retraining, dietary changes, pharmacologic interventions that includes at least two anticholinergics).
- II. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has been medically proven to be effective and therefore, **medically appropriate** in patients with fecal incontinence when ALL the following indications have been met:
  - A. Chronic fecal incontinence of greater than 2 episodes per week with a duration greater than 6 months (or 12 months if occurring after vaginal childbirth); AND
  - B. Documented failure of conservative therapies (e.g., pharmacologic treatments, dietary changes) performed for more than 12 months; AND
  - C. Incontinence is not related to an anorectal malformation, chronic inflammatory bowel disease, or a neurologic condition such as peripheral neuropathy or complete spinal cord injury.
- III. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has not been proven medically effective and is considered **investigational** for all other indications, including but not limited to, for the following conditions:
  - A. stress incontinence,
  - B. urge incontinence due to a neurological condition (e.g., diabetic neuropathy, multiple sclerosis, spinal cord injury);
  - C. other types of chronic voiding dysfunction;
  - D. constipation; or
  - E. chronic pelvic pain.

*Refer to Corporate Medical Policy #1.01.19 regarding Pelvic Floor Stimulation as a Treatment for Urinary Incontinence.*

*Refer to Corporate Medical Policy # 7.01.66 regarding Radiofrequency Treatment for Fecal Incontinence.*

*Refer to Corporate Medical Policy #8.01.22 regarding Posterior Tibial Nerve Stimulation.*

*Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.*

## **POLICY GUIDELINES:**

- I. Prior to permanent implantation, patients must demonstrate an appropriate response to test stimulation. An appropriate response is defined as at least a 50% improvement in voiding/incontinence symptoms, or a 50% decrease in residual urine volume.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

*Proprietary Information of Excellus Health Plan, Inc.*

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## **DESCRIPTION:**

Urinary voiding dysfunction is usually defined as the inability to control urination. Urinary voiding disorders are generally divided into five types, depending on the pathophysiology involved: urge incontinence—a subtype is urgency-frequency syndrome, overflow incontinence, also known as urinary retention, stress incontinence, mixed incontinence, and functional incontinence. 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. The term “overactive” bladder is frequently used when describing the symptoms of urgency-frequency and urge incontinence. Urinary retention is the inability to completely empty the bladder of urine.

Sacral nerve stimulation (SNS), or sacral nerve neuromodulation, is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. The SNS 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.

Prior to implantation of the device, patients undergo a peripheral nerve stimulation test to estimate potential response to SNS. Approximately 63% of patients have a successful peripheral nerve evaluation. The permanent device is implanted under general anesthesia. The pulse generator is inserted in the lower abdomen.

Treatment using sacral nerve stimulation is one of several alternative modalities for patients with urinary urge incontinence, significant symptoms of urgency-frequency, or non-obstructive urinary retention who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

Sacral nerve stimulation is also under investigation and has been proposed as a treatment for fecal incontinence, chronic constipation and pelvic pain.

*Sacral Nerve Stimulation for urinary incontinence needs to be distinguished from anterior sacral nerve root stimulation, which is indicated for a neurogenic bladder (VOCARE Bladder System).*

## **RATIONALE:**

The Interstim® Sacral Nerve Stimulation System (Medtronic) received pre-market approval for use in urge incontinence in 1997 and for urgency/frequency and nonobstructive urinary retention in 1999. In March 2011, Medtronic Inc. received premarket approval from the FDA for the use of InterStim® Therapy System for the treatment of fecal incontinence in patients who have failed or cannot tolerate more conservative treatments.

There is sufficient scientific evidence to conclude that sacral nerve stimulation is safe and effective for the treatment of urgency/frequency and non-obstructive urinary retention that is not of neurogenic origin and that health outcomes are improved. Good outcomes have been achieved outside investigational settings. Overall clinical success rates, defined by at least a 50% reduction in voiding dysfunction symptoms were 72%, 83% and 88% for patients with urge incontinence, non-obstructive urinary retention and urinary urgency-frequency, respectively. The benefits of SNS have been reported to be sustained for up to 5 years in patients for whom there is long-term follow-up data available.

There is consistent and longer-term results from 2 large trials in 2010 (a prospective multicenter investigational trial with 120 patients and a European cohort of 177 patients) in support of sacral nerve stimulation for the treatment of fecal incontinence. Together with a randomized controlled trial with 12-month follow-up from 2008, evidence is considered sufficient for sacral nerve stimulation to be an option for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy. It should be emphasized that not all patients will benefit, and that the adverse event rate for this procedure, including serious adverse events, is high. Patients should therefore be provided with adequate information to make an informed choice regarding the potential risks and benefits of this procedure.

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There is insufficient published data to draw conclusions about the efficacy of sacral nerve stimulation for patients with urinary frequency/urgency or retention of neurologic origin. Studies focusing on the use of sacral nerve stimulation for constipation and pelvic pain consist mostly of small case series with follow-up of short duration. The safety and efficacy of sacral nerve stimulation for these newer indications have yet to be proven in well-designed clinical trials. Currently, these are not approved FDA indications.

**CODES:**      Number      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<b><u>CPT:</u></b>	64561	Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)
	64581	Incision for implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Incision and subcutaneous placement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
	95970	Electronic analysis of implanted neurostimulator pulse generator system; simple or complex brain, spinal cord, or peripheral (e.g. cranial nerve, peripheral nerve, autonomic nerve, neuromuscular), neurostimulator pulse generator/transmitter, without reprogramming
	95971	simple spinal cord, or peripheral neurostimulator pulse generator/transmitter with intraoperative or subsequent programming
	95972	complex spinal cord, or peripheral neurostimulator pulse generator/ transmitter, with intraoperative or subsequent programming, first hour
	95973	complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour

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<b><u>HCPCS:</u></b>	A4290	Sacral nerve stimulation test lead, each
	E0745	Neuromuscular stimulator, electronic shock unit
	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

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- L8684      Radiofrequency transmitter (external) for use with implantable sacral root stimulator 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
- L8689      External recharging system for battery (internal) for use with implantable neurostimulator

**ICD9:**

**Investigational codes:**

- 564.0              Constipation
- 625.9              Pelvic pain
- 788.32             Stress incontinence, male
- 788.34             Incontinence without sensory awareness
- 635.6              Stress incontinence, female

**ICD10:**

- K59.00-K59.09   Constipation (code range)
- R10.2              Pelvic and perineal pain
- N39.3              Stress incontinence (male or female)
- N39.42             Incontinence without sensory awareness

**Medically Appropriate Codes:**

**ICD9:**

- 787.6              Incontinence of feces
- 788.2-.29         Retention of urine
- 788.31             Urge incontinence
- 788.41             Urinary frequency

**ICD10:**

- N39.41             Urge incontinence
- R15.0-R15.9      Fecal incontinence (code range)
- R33.0-R33.9      Retention of urine (code range)
- R35.0              Frequency of micturition

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\*key article

**KEY WORDS:**

Interstim®, Neuromodulation, Urge incontinence, Urgency-frequency, Urinary retention.

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## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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There is currently a National Coverage Determination (NCD) for sacral nerve stimulation for urinary incontinence. Please refer to the following NCD website for Medicare Members:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>