

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	SACRAL NERVE STIMULATION
Policy Number	7.01.10
Category	Technology Assessment
Effective Date	11/19/99
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, 01/22/15, 01/21/16, 01/19/17, 01/18/18, 03/21/19
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

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 *OR* at least one anticholinergic and one beta-3 adrenergic agonist).
- 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 two (2) episodes per week with a duration greater than 6 months (or 12 months if occurring after vaginal childbirth); AND
 - B. Documented failure of prescribed conservative therapies (e.g., pharmacologic treatments, dietary changes) performed for more than three (3) 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; and
 - E. chronic pelvic pain.

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

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

Refer to Corporate Medical Policy #8.01.22 regarding Percutaneous Posterior Tibial Nerve Stimulation(PPTNS).

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

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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.

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.

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.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for 4 to 7 days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device. The second type of testing is a 2-stage surgical procedure. In the first stage, a quadripolar-tined lead is implanted (stage 1). The testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, they can proceed to stage 2 of the surgery, which is permanent implantation of the neuromodulation device. The 2-stage surgical procedure has been used in various ways. These include its use instead of PNE, for patients who failed PNE, for patients with an inconclusive PNE, or for patients who had a successful PNE to further refine patient selection. Approximately 63% of patients have a successful testing phase. The permanent device is implanted under general anesthesia, with the pulse generator inserted in the upper gluteal region.

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

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

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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.

In a practice bulletin for Urinary Incontinence in Women (2015), the American College of Obstetricians and Gynecologists (ACOG), suggests consideration of sacral neuromodulation for patients with recalcitrant urinary urge incontinence who have failed other conservative measures.

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 are 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.

Bharucha and colleagues (2017) published American Gastroenterological Association (AGA) clinical practice update expert review of best practices for the management of fecal incontinence using surgical interventions and device aided therapy. They advise sacral nerve stimulation should be considered for patients with moderate to severe fecal incontinence in whom symptoms have not responded after a 3 month or longer trial of conservative measures. In addition, the authors found no evidence that SNS improves bowel symptoms or rectal evacuation in defecatory disorders.

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

- *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.*

CPT Codes

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement 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

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Code	Description
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

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Code	Description
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), non-high frequency with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
E0745	Neuromuscular stimulator, electronic shock unit
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
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, replacement only

ICD10 Codes**Medically Appropriate Codes:**

Code	Description
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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ICD10 Codes Investigational Codes:

Code	Description
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

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*Key Article

KEY WORDS

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

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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&>