

Table of Contents

1.0	Description of the Procedure, Product, or Service.....	1
2.0	Eligible Recipients.....	2
2.1	General Provisions.....	2
3.0	When the Procedure, Product, or Service Is Covered.....	2
3.1	General Criteria.....	2
3.2	Specific Criteria.....	2
4.0	When the Procedure, Product, or Service Is Not Covered.....	3
4.1	General Criteria.....	3
4.2	Specific Criteria.....	3
4.3	Other Medical Policy Guidelines.....	3
5.0	Requirements for and Limitations on Coverage.....	5
5.1	Prior Approval.....	5
6.0	Providers Eligible to Bill for the Procedure, Product, or Service.....	5
7.0	Additional Requirements.....	5
7.1	Compliance.....	5
8.0	Policy Implementation/Revision Information.....	6
	Attachment A: Claims-Related Information.....	7
A.	Claim Type.....	7
B.	Diagnosis Codes.....	7
C.	Procedure Code(s).....	7
D.	Modifiers.....	8
E.	Billing Units.....	8
F.	Place of Service.....	8
G.	Co-payments.....	8
H.	Reimbursement.....	8

1.0 Description of the Procedure, Product, or Service

Sacral nerve stimulation (SNS), also referred to as sacral nerve neuromodulation (SNM), is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This policy addresses use of SNS in the treatment of urinary or fecal incontinence, urinary or fecal nonobstructive retention, or chronic pelvic pain.

Sacral nerve stimulation treatment is one of several alternative modalities for recipients with either urinary urge incontinence, significant symptoms of urgency-frequency, or nonobstructive urinary retention who have failed behavioral (e.g. prompted voiding) and/or pharmacologic therapies. 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. Urinary retention is the inability to completely empty the bladder of urine.

The SNM 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 recipient 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 permanent device, recipients undergo a peripheral nerve stimulation test to estimate potential response to SNM. This procedure is done 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 several days. This lead is connected to an external stimulator, which is carried by recipients in their pocket or on their belt. Recipients then keep track of voiding symptoms while the temporary device is functioning. The results of this test phase are used to determine whether recipients are appropriate candidates for the permanent device. If recipients show a 50% or greater reduction in incontinence frequency, they are deemed eligible for the permanent device. According to data from the manufacturer, approximately 63% of recipients have a successful peripheral nerve evaluation and are thus candidates for the permanent SNM.

The permanent device is implanted with the recipient under general anesthesia. An incision is made over the lower back, and the electrical leads are placed in contact with the sacral nerve root(s). The wire leads are extended through a second incision underneath the skin across the flank to the lower abdomen. Finally, a third incision is made in the lower abdomen where the pulse generator is inserted and connected to the wire leads. Following implantation, the physician programs the pulse generator to the optimal settings for that recipient. The recipient can switch the pulse generator between on and off by placing the control magnet over the area of the pulse generator for 1–2 seconds.

In 1997, the Medtronic Interstim Sacral Nerve Stimulation system received U.S. Food and Drug Administration (FDA) approval for marketing for the indication of urinary urge incontinence in recipients who have failed or could not tolerate more conservative treatments. In 1999, the device

received FDA approval for the additional indications of urgency-frequency and urinary retention in recipients without mechanical obstruction. There has also been research interest in using the device as a treatment of fecal incontinence, constipation, and chronic pelvic pain.

In 2006, the Medtronic Interstim® II System received U.S. Food and Drug Administration (FDA) approval for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original system and is reported to be suited for those with lower energy requirements or small stature. The device also includes updated software and programming options. All other uses of this device (e.g., fecal incontinence or constipation) would be off-label.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

Note: Most children will be able to get all the services they need under the core (basic) plan of NC Health Choice. A child who qualifies as having special needs may be able to receive additional services not covered by the core plan.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Sacral nerve neuromodulation/stimulation for pelvic floor dysfunction is covered under the NC Health Choice Program when it is determined to be medically necessary for the treatment of urge incontinence, urgency-frequency, and non-obstructive urinary retention when ALL of the following criteria are met:

- a. documented failure or intolerance to conventional therapy (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy);
- b. the recipient is an appropriate surgical candidate;

- c. a successful percutaneous test stimulation defined as at least 50% improvement in symptoms was performed; **AND**
- d. the condition is not related to a neurologic condition.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Sacral nerve neuromodulation/stimulation for pelvic floor dysfunction is not covered in the following situations:

- a. Urinary/voiding applications of sacral nerve neuromodulation other than those listed in **Subsection 3.2** are considered investigational, including but not limited to treatment of the following:
 - 1. stress incontinence;
 - 2. urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis or spinal cord injury);
 - 3. other types of chronic voiding dysfunction;
 - 4. recipients with mechanical urethral obstruction such as benign prostatic hypertrophy, cancer or urethral stricture;
 - 5. conditions which have responded to behavioral and pharmacological interventions.
- b. Sacral nerve neuromodulation is also investigational in the treatment of fecal incontinence, chronic constipation, or chronic pelvic pain.

4.3 Other Medical Policy Guidelines

- a. Urinary Incontinence

According to the manufacturer of the InterStim® System for Urinary Control (Medtronic, Inc., Minneapolis, MN), sacral nerve stimulation is not intended for recipients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture. Medtronic also includes the following statement regarding Precautions/Adverse Events on their website:

“Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for

patients with neurological disease origins such as multiple sclerosis. The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. ”

One industry-funded study reported 11-year [three (3) to 162 months] follow-up on 234 recipients who had undergone placement of an implantable pulse generator. Fifty-four percent of the recipients consented and returned a mailed questionnaire. Of these, 104 charts were available for review (44% of the total recipient population). Recipients presenting with urinary frequency and/or urinary incontinence (n=83) showed significant improvements in the standard outcome measures (voids, leaks, pads). In contrast, the 21 recipients presenting with non-obstructive urinary retention, half of which were attributable to a neurological disorder, showed improvement only in one (1) of five (5) outcome measures (from 1.7 voids per night to 1.0). Another retrospective case series reported four (4)- to 32-month follow-up on 33 recipients with neurologic disease (16 multiple sclerosis, six (6) Parkinson’s disease, two (2) spina bifida, two (2) cerebrovascular accident, one (1) cerebral palsy, or six (6) other) who underwent sacral nerve stimulation for neurogenic lower urinary tract dysfunction. Twenty-eight of the recipients (85%) had a successful test stimulation trial [$> 50\%$ reduction leakage episodes, nocturnal, or pad usage over a period of one (1) to three (3) weeks] with subsequent implantation of the pulse generator. Sacral stimulation resulted in an average 68% decrease in incontinence episodes (from 4 to 1.3 per 24 hours) and night-time voids (from 2.6 to 0.8 per night), and a 72% reduction in the number of pads used per 24 hours (from 3.5 to 1.0). These results suggest that sacral nerve stimulation may have short-term efficacy in recipients with underlying neurologic disease who have had successful test stimulation. However, as the authors noted, “long-term efficacy of sacral nerve neuromodulation in these recipients needs further research because neurologic diseases, such as MS and Parkinson disease are typically progressive and hence may have variable responses over time.” Thus, longer follow-up in a larger number of recipients is needed.

White et al. reported complications from a prospective longitudinal analysis of 202 recipients with urge incontinence, urinary urgency, or urinary retention who had been treated with sacral nerve stimulation between 2001 and 2008. At a mean follow-up of 37 months (range 7-84), 67 recipients (30%) had experienced adverse events that required either lead or implantable pulse generator revisions. Complications included pain (3%), device malfunction secondary to trauma (9%), infection (4%), postoperative hematoma (2%) and lead migration (6%). In addition, 5% of recipients underwent elective removal, 4% had device removal due to lack of efficacy, and 2% required removal due to battery expiration. At the last follow-up, 172 recipients (85%) had functional implanted units.

A 2009 Cochrane review described eight (8) randomized studies on implanted devices for urinary storage and voiding dysfunction in adults. In spite of methodological problems (generally poor quality studies), the evidence, “seems clear that continuous stimulation offers benefits for carefully selected people with overactive bladder syndrome and for those with urinary retention but no structural

obstruction.” The authors concluded that while some people benefit, more research is needed to improve recipient selection, to carry out the implant, and to find why so many fail.

b. Fecal Incontinence and Constipation

Recent literature indicates increasing study of sacral nerve stimulation for the treatment of fecal incontinence and constipation, particularly from outside of the U.S. Identification of recipients who will respond to sacral nerve stimulation remains problematic, and the evidence remains insufficient to determine the effect of this technology on net health outcomes.

c. Chronic Pelvic Pain

Siegel and colleagues reported on a case series of ten (10) recipients with chronic pelvic pain. Their research interest was prompted by the concomitant decrease in pain reported by recipients receiving sacral neuromodulation for urinary disorders. The authors did not detail the etiology of the pain syndromes in their case series, but reported that 9 of the 10 recipients had a decrease in pain. These data are inadequate to permit scientific conclusions..

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

- a. Prior approval is not required for implantation of the sacral nerve Neuromodulation/stimulation device.
- b. Prior approval is required for durable medical equipment for which the reimbursement is \$1000 or more (purchase or rental to purchase price).

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
September 30, 2011	Throughout	Policy Date of Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines..

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Code(s)	
64561	sacral nerve (transforaminal placement)
64581	sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrodes
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
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	simple spinal cord, or peripheral (ie, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	complex spinal cord, or peripheral (except cranial nerve) 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 (List separately in addition to code for primary procedure)
HCPCS Code(s)	
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
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator 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

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital, Outpatient Hospital and Home

G. Co-payments

Refer to NCHC General Policy Number NCHC 2009.01, Co-pays.

H. Reimbursement

Providers must bill their usual and customary charges.