MEDICAL POLICY

POLICY TITLE	SACRAL NERVE NEUROMODULATION/STIMULATION AND PELVIC FLOOR STIMULATION DEVICES
POLICY NUMBER	MP- 1.033

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I. POLICY

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Urinary Incontinence and Non-obstructive Retention

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in patients who meet all of the following criteria:
   1. There is a diagnosis of at least one of the following:
      a) Urge incontinence
      b) Urgency-frequency
      c) Non-obstructive urinary retention
   2. There is documented failure or intolerance to at least two conventional therapies (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)
   3. The patient is an appropriate surgical candidate
   4. Incontinence is not related to a neurologic condition

B. Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in patients who meet all of the following criteria:
   1. All of the criteria in A (1-4) above are met.
   2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 1 week.

Other urinary/voiding applications of sacral nerve neuromodulation are considered **investigational**, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition, e.g., detrusor hyperreflexia, multiple sclerosis, spinal

cord injury, or other types of chronic voiding dysfunction. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Fecal Incontinence

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in patients who meet all of the following criteria:
    1. There is a diagnosis of chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth.
    2. There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, performed more than 12 months [or 24 months in case of cancer] previously).
    3. The patient is an appropriate surgical candidate.
    4. The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease.
    5. Incontinence is not related to a neurologic condition.
B. Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in patients who meet all of the following criteria:
    1. All of the criteria in A (1-5) above are met.
    2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 1 week.

Sacral nerve neuromodulation is **investigational** in the treatment of chronic constipation or chronic pelvic pain. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Pelvic Floor Stimulation

Non- invasive *electrical* pelvic floor stimulation devices for the treatment of stress and/or urge urinary incontinence are considered **medically necessary** when the following criteria are met:

- The patient is cognitively intact;
- The patient has failed a documented trial of pelvic muscle exercise (PME) training*.

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*__Note__: A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

Non-invasive *electrical* stimulator devices used for the treatment of fecal incontinence are considered **investigational.**

Non-invasive *magnetic* pelvic stimulator devices used for the treatment of urinary and fecal incontinence are considered **investigational.**

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Cross-reference

MP-6.020 Transcutaneous Electrical Nerve Stimulation
MP-1.077 Stimulation of the Sacral Anterior Root Combined with Posterior Sacral Rhizotomy in Patients with Spinal Cord Injury
MP-4.012 Urinary Incontinence Treatment (Including Periurethral Bulking Agents)
MP- 6.045 Sympathetic Therapy for the Treatment of Pain
MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP-6.047 Interferential Stimulation for Treatment of Pain
MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
MP-6.049 H-Wave Electrical Stimulation
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy
MP-6.051 Neuromuscular and Functional Neuromuscular Electrical Stimulation

II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[Y] SeniorBlue HMO*
[Y] SeniorBlue PPO*
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO**

* Refer to Novitas Solutions Local Coverage Determination (LCD) L34707 Sacral Nerve Stimulation. .

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**Refer to FEP Medical Policy Manual MP- 7.01.69 Sacral Nerve Neuromodulation/Stimulation and 1.01.17 Pelvic Floor Stimulation as a Treatment of Urinary Incontinence The FEP Medical Policy Manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND

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Sacral Nerve Neuromodulation/Stimulation

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.

Background

Treatment using sacral nerve neuromodulation (SNM) is one of several alternative modalities for patients with fecal or urinary incontinence (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 and is a prominent symptom of interstitial cystitis (also called bladder pain syndrome). Urinary retention is the inability to completely empty the bladder of urine. Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

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 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 permanent device, patients undergo a peripheral nerve stimulation test to estimate potential response to SNM. 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 several days. This lead is connected to an external stimulator, which is

carried by patients in their pocket or on their belt. Patients then keep track of their voiding symptoms while the temporary device is functioning. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device. According to data from the manufacturer, approximately 63% of patients have a successful peripheral nerve evaluation and are thus candidates for the permanent SNM.

The permanent device is implanted with the patient 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 patient. The patient 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.

Regulatory Status

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 patients 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 patients without mechanical obstruction.

In 2006, the Medtronic Interstim II System received 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.

In 2011, the Medtronic Interstim System received FDA approval for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.

Pelvic Floor Stimulation

Pelvic floor stimulation (PFS) is proposed as a nonsurgical treatment option for women and men with urinary incontinence. This approach involves either electrical stimulation of pelvic floor musculature or extracorporeal pulsed magnetic stimulation.

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Background

Urinary incontinence is a common condition defined as an involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects quality of life and treatment decisions. The types of urinary incontinence include stress, urge, overflow, functional, and post-prostatectomy incontinence. Nonsurgical treatment options may include pharmacologic treatment, pelvic muscle exercises (PME), bladder training exercises, electrical stimulation, and neuromodulation.

Pelvic floor stimulation (PFS) involves the electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation or, more recently, extracorporeal electromagnetic (also called magnetic) pulses. The intent of the intervention is to stimulate the pudendal nerve in order to activate the pelvic floor musculature; it is thought that activation of these muscles will lead to improved urethral closure. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation.

The methods of electrical PFS have varied in location (e.g., vaginal, rectal), stimulus frequency, stimulus intensity or amplitude, pulse duration, pulse to rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, and overall time period for device use between clinical and home settings. Variation in the amplitude and frequency of the electrical pulse is used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the type of etiology of incontinence, i.e., either detrusor instability, stress incontinence, or a mixed pattern. Magnetic PFS does not require an internal electrode; patients may sit, fully clothed, on a specialized chair.

Patients receiving electrical PFS may undergo treatment in a physician's office or physical therapy facility, or patients may undergo initial training in a physician's office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS may be delivered in the physician's office.

Regulatory Status

In June 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus, Inc) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for treating urinary incontinence in women. This device was formerly known as the Neotonus Model 1000 Magnetic Stimulator, and it provides noninvasive electromagnetic stimulation of pelvic floor musculature. The magnetic system is embedded in a chair seat; patients sit on the chair fully clothed and receive the treatment. The magnetic fields are controlled by a separate power unit.

Several electrical stimulators have also been cleared by the FDA. In March 2006, the MyoTrac Infiniti™ (Thought Technology, Ltd.), a nonimplanted electrical stimulator for urinary incontinence, was cleared for marketing by the FDA through the 510(k) process. Predicate devices, also used to treat urinary incontinence, include the Pathway™ CTS 2000 (Prometheus Group) and the InCare PRS (Hollister Inc.).

IV. DEFINITIONS

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EXTRACORPOREAL MAGNETIC INNERVATION (ExMI TM) is a technology used to deliver non-invasive electromagnetic stimulation to the muscles of pelvic floor to strengthen and improve neuromuscular control for the treatment of urinary incontinence in women.

PUDENDAL refers to external female genitalia.

INNERVATION is defined as nerve supply to a specific part of the body.

STRESS INCONTINENCE is the involuntary leaking of urine during activities that increase pressure inside the abdomen, such as coughing, sneezing, or jogging.

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.

URINARY RETENTION is the inability to completely empty the bladder of urine.

V. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

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VI. DISCLAIMER

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Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

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Other sources

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VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
64561	64581	64585	64590	64595	95970	95971		

HCPCS Code	Description
A4290	SACRAL NERVE STIMULATION TEST LEAD, EACH
C1767	GENERATOR, NEUROSTIMULATOR (IMPLANTABLE), NON-RECHARGEABLE
C1778	LEAD, NEUROSTIMULATOR (IMPLANTABLE)
C1883	ADAPTOR/EXTENSION, PACING LEAD OR NEUROSTIMULATOR LEAD (IMPLANTABLE)
C1897	LEAD, NEUROSTIMULATOR TEST KIT (IMPLANTABLE)
E0740	INCONTINENCE TREATMENT SYSTEM, PELVIC FLOOR STIMULATOR, MONITOR, SENSOR AND/OR TRAINER
E0745	NEUROMUSCULAR STIMULATOR, ELECTRONIC SHOCK UNIT
E1399	DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS
L8680	IMPLANTABLE NEUROSTIMULATOR ELECTRODE, EACH
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

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ICD-9-CM Diagnosis Code*	Description
787.6	INCONTINENCE OF FECES
788.20	UNSPECIFIED RETENTION OF URINE
788.21	INCOMPLETE BLADDER EMPTYING
788.29	OTHER SPECIFIED RETENTION OF URINE
788.32	STRESS INCONTINENCE, MALE
788.33	MIXED INCONTINENCE URGE AND STRESS (MALE)(FEMALE)
788.41	URINARY FREQUENCY
788.42	POLYURIA
788.43	NOCTURIA

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
R15.9	Full incontinence of feces
R33.9	Retention of urine, unspecified
R39.14	Feeling of incomplete bladder emptying
R33.8	Other retention of urine
N39.3	Stress incontinence (female) (male)
N39.46	Mixed incontinence
R35.Ø	Frequency of micturition
R35.8	Other polyuria
R35.1	Nocturia
F98.0	Enuresis not due to a substance or known physiological condition
N39.41-N39.498	Other specified urinary incontinence

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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MP 6.024	**CAC 5/27/03**
	CAC 12/14/04
	CAC 11/29/05
	CAC 11/28/06
	CAC 1/29/08
	J12 MAC 12/12/08
	CAC 1/27/09 Consensus
	CAC 9/29/09 Added Medically Necessary criteria for electrical pelvic floor stimulation device for urinary incontinence
	CAC 9/27/10 Added medical necessity criteria for sacral nerve neuromodulation/ stimulation for fecal incontinence; previously considered investigational.
	CAC 10/25/11 Adopted BCBSA for Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction. Deleted medically necessary criteria for symptoms present for one year and resulting in limitation of patient's ability to work or participate in activities outside the home. Deleted requirement for a trial of 2 anticholinergic drugs or combination of anticholinergic and a tricyclic antidepressant. Added criteria for a documented treatment failure or intolerance to conventional therapy. Added criteria to include a pharmacologic trial for at least a sufficient duration to fully assess its efficacy. Added requirement for a successful percutaneous test trial defined as at least 50% improvement in symptoms over a period of at least 2 weeks. Medicare variation added to NCD 230.14.
	CAC 10/30/12 Minor revision. For sacral nerve modulation/stimulation for urinary incontinence, implantable lead stimulation was added as an alternative to percutaneous test stimulation for eligible patients within medically necessary policy statements. Medically necessary policy statement for urinary incontinence changed to 2-part statement (has criteria for test stimulation and for permanent implantation). The FEP variation was revised to refer to the FEP manual. Codes reviewed 9/24/12 klr
	CAC 11/26/13 Minor revision. For sacral nerve modulation/stimulation, the length of successful percutaneous test stimulation is medically necessary statements changed from at least 2 weeks to at least 1 week. Fecal incontinence policy statement separated into 2 statements; 1 on trial stimulation and 1 on permanent implantation. Edits made to statements so that criteria for fecal and urinary incontinence are similar, when applicable. There were no changes to pelvic floor stimulation, References updated. FEP variation revised.
	7/24/14 Administrative Change. Changed Medicare variation.Referenced NCD 230.18 – changed to LCD L34707 Sacral Nerve Stimulation. Fecal incontinence now added in the LCD. Criteria for urinary incontinence matches the NCD.

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