

Corporate Medical Policy

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

File Name: pelvic_floor_stimulation_as_a_treatment_of_urinary_incontinence
Origination: 5/2001
Last CAP Review: 11/2011
Next CAP Review: 11/2012
Last Review: 11/2011

Description of Procedure or Service

A variety of non-surgical approaches has been investigated as treatment of urinary incontinence, including pelvic floor muscle exercises (PME), biofeedback, other behavioral therapies, and pelvic floor stimulation. 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 pulsed magnetic innervation. It is thought that pelvic floor stimulation of the pudendal nerve will improve urethral closure by activating the pelvic floor musculature. 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 pelvic floor stimulation does not require an internal electrode; patients may sit, fully clothed, on a specialized chair.

Pulsed magnetic neuromodulation utilizes extracorporeal magnetic innervation (ExMI™) technology to deliver nerve impulses to the pelvic floor area to increase muscular contractions in an attempt to improve bladder control. The NeoControl® Pelvic Floor Therapy System is a marketed device that employs technology for the treatment of urinary incontinence in women.

The INNOVA Feminine Incontinence Treatment System is a pelvic floor stimulator device designed for home treatment of urinary incontinence. Magnetic PFS may be delivered in the physician's office.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will not provide coverage for Pelvic Floor Stimulation. It is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

When Pelvic Floor Stimulation as a Treatment of Urinary Incontinence is covered

Not Applicable

When Pelvic Floor Stimulation as a Treatment of Urinary Incontinence is not covered

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for urinary incontinence is considered investigational.

Policy Guidelines

Available data are insufficient to determine whether this treatment is as effective as alternatives. Additionally, the treatments lack standardization of delivery. There are minimal data for magnetic stimulation and no randomized trials. There is insufficient medical and scientific evidence to permit the Plan to evaluate the therapeutic value of pelvic floor stimulation as a treatment of urinary incontinence. For further information, please refer to separate BCBSNC policy titled, "Investigational (Experimental) Services".

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: E0740

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

New policy entitled: Treatment of Urinary Incontinence

BCBSA TEC Evaluation, June 2000; Volume 15, No. 2

BCBSA TEC Evaluation, August 2000; Volume 15, No. 8

BCBSA Medical Policy Reference Manual, 12/15/00; 1.01.17

Specialty Matched Consultant Advisory Panel - 5/2001

Specialty Matched Consultant Advisory Panel - 9/2001

BCBSA Medical Policy Reference Manual, 2/15/02; 7.01.69

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BCBSA Medical Policy Reference Manual, 12/18/02; 7.01.69

BCBSA Medical Policy Reference Manual, 12/18/02; 1.01.17

BCBSA Medical Policy Reference Manual, 4/29/03; 7.01.19

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 11/9/04

Specialty Matched Consultant Advisory Panel - 5/2005

New policy entitled: Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 3/15/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 3/7/06.

Specialty Matched Consultant Advisory Panel - 5/2007.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 9/18/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/24/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 6/11/09.

Specialty Matched Consultant Advisory Panel - 9/2009

Gilling PJ, Wilson LC, Westenberg AM et al. A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs sham therapy in the treatment of women with stress urinary incontinence. BJU Int 2009; 103(10):1386-90.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/8/10

Specialty Matched Consultant Advisory panel review 12/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/14/11

Medical Director review 6/2011

Specialty Matched Consultant Advisory Panel review 11/2011

Policy Implementation/Update Information

New policy entitled: Treatment of Urinary Incontinence

5/01 Policies combined and renamed. Added criteria for Pelvic Floor Stimulation as a Treatment of Urinary Incontinence. Specialty Matched Consultant Advisory Panel. No changes to policy.

9/01 Specialty Matched Consultant Advisory Panel review. Added description and coverage

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

- criteria for carbon-coated spheres or beads for Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence.
- 10/01 Coding format changes.
- 3/02 Added codes 64561 and 64581 to the Billing/Coding Section in Section II Sacral Nerve Stimulation for Urinary Incontinence and System Application Guidelines.
- 4/02 Format changes.
- 11/03 Specialty Matched Consultant Advisory Panel review 5/23/03. Benefits Application section revised. For Section I, Periurethral Injection of Implant Material, revised description for clarity; revised Policy Guidelines to indicate that “Patients whose incontinence does not improve with five injection procedures....”. For Section II, Sacral Nerve Stimulation, removed codes 64555, 64575, E0751, E0753, E1399 and added codes 95971, E0752 and E0759. For Section III, Pelvic Floor Stimulation, revised description for clarity; added Innova Feminine Incontinence Treatment System to this section; added code 0029T to Billing/Coding section and removed codes 97014 and 97032. Deleted Section IV, Innova Feminine Incontinence Treatment System.
- 2/04 Added HCPCS codes L8603 and Q3031 to Billing/Coding section of Section I re: Periurethral Injection of Implant Material.
- 6/16/05 Specialty Matched Consultant Advisory Panel review 5/24/05. Section I - Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence; description revised, included biocompatible copolymer implant (e.g., URYX) in description; For “When Covered”- 2.d. “Cross-linked collagen or carbon-coated beads are used as the implantable material.” pulled out as a separate sentence so need 1 or 2 and use of listed materials; also added biocompatible copolymers as one of the approved materials; For “When not Covered” added “The use of autologous fat and autologous ear chondrocytes as periurethral bulking agents are considered investigational and are not covered.”; For “Policy Guidelines” removed sentence re: “15 ml of paste are injected...” since the procedure is included in the description. Section II - Sacral Nerve Modulation/Stimulation...description of procedure revised to provide additional information; For “When Covered” - changed #2 to indicate that the urinary incontinence conditions listed in #1 should not be related to a neurologic condition; #3 now reads: “Medical records document that the patient has failed at least a 3 month trial of conservative treatment such as behavioral therapy (i.e., diet modification, bladder training, biofeedback, Kegel exercises) and/or pharmacotherapy (i.e., 2 or more anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant); #4 is now re: the percutaneous test stimulation. For “When not Covered” #1 - added several examples of conditions “Any conditions other than those listed above including but not limited to the following: stress incontinence, urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis or spinal cord injury), other types of chronic voiding dysfunction, patients with mechanical urethral obstruction such as benign prostatic hypertrophy, cancer or urethral stricture.” Section III - Pelvic Floor Stimulation...added policy guidelines re: investigational status: “Available data are insufficient to determine whether this treatment is as effective as alternatives. Additionally, the treatments lack standardization of delivery. There are minimal data for magnetic stimulation and no randomized trials. There is insufficient medical and scientific evidence to permit the Plan to evaluate the therapeutic value of pelvic floor stimulation as a treatment of urinary incontinence. For further information, please refer to separate policy number MED1263, Investigational (Experimental) Services.” Added - Section IV re: Transvaginal Radiofrequency Bladder Neck Suspension for Urinary Stress Incontinence as investigational. Notice given 6/16/05. Effective date 8/18/05.

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- 1/5/06 Removed deleted codes E0752, E0756, E0757, E0758 & E0759 from appropriate Billing/Coding sections.
- 2/26/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689 to Section II-Sacral Nerve Modulation/Stimulation for Urinary Incontinence. (pmo)

New policy entitled: Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

- 6/4/07 Section III (Pelvic Floor Stimulation as a Treatment of Urinary Incontinence) of the policy entitled “Urinary Incontinence, Treatment” issued as a separate policy entitled “Pelvic Floor Stimulation as a Treatment of Urinary Incontinence”. No changes to criteria. (pmo)
- 1/05/09 Under Billing/Coding section, removed CPT code 0029T. Code will be deleted as of 12/31/08. (pmo)
- 9/28/09 Description section updated. Policy statement clarified. Reference sources added.(pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 1/18/11 Specialty Matched Consultant Advisory Panel review 12/2010. References updated. Changed Policy Statement from “BCBSNC will not provide coverage for electrical or magnetic stimulation of the pelvic floor muscles” to: “BCBSNC will not provide coverage for Pelvic Floor Stimulation. It is considered investigational. BCBSNC does not cover investigational services.” (mco)
- 6/21/11 Medical Director review 6/2011. References updated. No changes to policy statements. (mco)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. No changes to Policy Statements. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.