

## Corporate Medical Policy

### Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

**File Name:** pelvic\_floor\_stimulation\_as\_a\_treatment\_of\_urinary\_and\_fecal\_incontinence  
**Origination:** 5/2001  
**Last CAP Review:** 11/2018  
**Next CAP Review:** 11/2019  
**Last Review:** 11/2018

#### **Description of Procedure or Service**

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Pelvic floor stimulation (PFS) is proposed as a nonsurgical treatment option for individuals with urinary incontinence. This approach involves either electrical stimulation of pelvic floor musculature or extracorporeal pulsed magnetic stimulation. Electrical stimulation of the pelvic floor is also proposed as a treatment of fecal incontinence.

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 to activate the pelvic floor musculature; it is thought that activation of these muscles will improve 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; instead, patients sit fully clothed on a specialized chair with an embedded magnet.

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.

PFS was first proposed as a treatment for urinary incontinence and later for fecal incontinence. Incontinence, especially urinary, is a common condition and can have a substantial impact on quality of life. Nonsurgical treatment options for incontinence may include pharmacologic therapy, pelvic floor muscle exercises, bowel or bladder training exercises, electrical stimulation, and neuromodulation.

#### **Regulatory Status**

Several electrical stimulators have been cleared by the U.S. Food and Drug Administration (FDA). In March 2006, the MyoTrac Infiniti™ (Thought Technology, Ltd.) and in 2015, the ApexM (InControl Medical), nonimplanted electrical stimulators for treating urinary incontinence, were cleared for marketing by the FDA through the 510(k) process.

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Predicate devices, also used to treat urinary incontinence, include the Pathway™ CTS 2000 (Prometheus Group) and the InCare® PRS (Hollister Inc.). In 2011, the itouch Sure Pelvic Floor Exerciser (TensCare, U.K.) was cleared for marketing. This product is being marketed in the U.S. as EmbaGYN® by Everett Laboratories (Chatham, NJ).

In June 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus, Inc) was approved by the FDA through the premarket approval process for treating urinary incontinence in women. This device, formerly known as the Neotonus Model 1000 Magnetic Stimulator, 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.

In February 2014, the InTone®MV (InControl Medical; Brookfield, WI), a nonimplantable device that provides electrical stimulation and/or biofeedback via manometry, was cleared by the FDA. The device is intended for the treatment of male and female urinary and fecal incontinence.

## Related Policies:

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction  
Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction

***\*\*\*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**

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**Pelvic Floor Stimulation is considered investigational. BCBSNC does not provide coverage for investigational services.**

## **Benefits Application**

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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.

## **When Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence is covered**

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Not Applicable

## **When Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence is not covered**

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

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

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## Policy Guidelines

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For individuals who have urinary incontinence who receive electrical PFS, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Findings from multiple RCTs have not found that electrical PFS used to treat urinary incontinence in women consistently improved the net health outcome compared with placebo or other conservative treatments. Meta-analyses of these RCTs have had mixed findings. Moreover, meta-analyses of RCTs have not found a significant benefit of electrical PFS in men with postprostatectomy incontinence compared with a control intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive electrical PFS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Several RCTs have evaluated electrical PFS to treat fecal incontinence. Only one trial was sham-controlled, and it did not find that electrical stimulation improved the net health outcome. Systematic reviews of RCTs have not found that electrical stimulation is superior to control interventions for treating fecal incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have urinary incontinence who receive magnetic PFS, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review of RCTs on magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the small number of trials with short-term follow-up, methodologic limitations, and heterogeneity in terms of patient populations, interventions, and outcomes reporting. There was only one RCT evaluating magnetic stimulation for treating men with postprostatectomy urinary incontinence. It reported short term results favoring magnetic PFS; however, the trial was small and lacked a sham comparator. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive magnetic PFS, the evidence includes no RCTs or non-RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Billing/Coding/Physician Documentation Information

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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](http://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

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**New policy entitled: Treatment of Urinary Incontinence**

# Pelvic Floor Stimulation as a Treatment of Urinary and Fecal 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

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

# Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

Specialty Matched Consultant Advisory Panel review 11/2011

Wallis MC, Davies EA, Thalib L et al. Pelvic static magnetic stimulation to control urinary incontinence in older women: a randomized controlled trial. Clin Med Res 2012; 10(1):7-14. Retrieved on May 15, 2012 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3280454/?tool=pubmed>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/12/12

Specialty Matched Consultant Advisory Panel review 11/2012

Lucas MG, Bosch RJ, Burkhard FC et al. EAU guidelines on assessment and nonsurgical management of urinary incontinence. Eur Urol 2012; 62(6):1130-42. Retrieved from <http://www.elsevier.es/en/revistas/actas-urologicas-espa%C3%B1olas-292/european-association-of-urology-guidelines-on-assessment-90196207-articulo-especial-2013>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/11/13

National Institute for Health and Clinical Excellence (NICE): National Clinical Guideline Centre (UK). Urinary Incontinence in Neurological Disease: Management of Lower Urinary Tract Dysfunction in Neurological Disease. August 2012. Retrieved from <http://www.ncbi.nlm.nih.gov/books/NBK132841/>

Specialty Matched Consultant Advisory Panel review 11/2013

Medical Director review 11/2013

## **Policy re-titled: Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence**

Shamliyan T, Wyman J, Kane R. Agency for Healthcare Research and Quality (AHRQ): Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness. 2012. <http://effectivehealthcare.ahrq.gov/ehc/products/169/834/urinaryincontinence-treatment-report-130909.pdf>.

Vonthein R, Heimerl T, Schwandner T et al. Electrical stimulation and biofeedback for the treatment of fecal incontinence: a systematic review. Int J Colorectal Dis 2013; 28(11):1567-77.

National Institute for Health and Clinical Excellence (NICE). Faecal incontinence: the management of faecal incontinence in adults. 2007. Available online at: <http://www.nice.org.uk/CG49>.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/10/14

Medical Director review 5/2014

Specialty Matched Consultant Advisory Panel review 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/23/15

Specialty Matched Consultant Advisory Panel review 11/2015

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American Urological Association. Diagnosis and Management of Overactive Bladder (Non-Neurogenic) in Adults. 2014; <https://www.auanet.org/common/pdf/education/clinical-guidance/Overactive-Bladder.pdf>. Accessed October 12, 2016.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 10/13/2016

Specialty Matched Consultant Advisory Panel review 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 8/10/2017

Specialty Matched Consultant Advisory Panel review 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 8/9/2018

Specialty Matched Consultant Advisory Panel review 11/2018

## **Policy Implementation/Update Information**

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### **New policy entitled: Treatment of Urinary Incontinence**

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|---------|---|
| 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 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   |

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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.

- 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

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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)
- 6/12/12 Description section updated. Policy Guidelines updated. References updated. Medical Director review 5/2012. (mco)
- 1/15/13 Specialty Matched Consultant Advisory Panel review 11/2012. Added “Related Policies” to Description section. No changes to Policy Statements. (mco)
- 5/28/13 References updated. No changes to Policy Statements. (mco)
- 12/10/13 Specialty Matched Consultant Advisory Panel review 11/2013. Medical Director review 11/2013. References updated. No changes to Policy Statements. (mco)

## **Policy re-titled: Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence**

- 5/27/14 Policy re-titled from “Pelvic Floor Stimulation as a Treatment of Urinary Incontinence” to “Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence.” Description section updated. Added the following statement to the “When not Covered” section: “Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for fecal incontinence is considered investigational.” Policy Guidelines updated. References updated. Medical Director review 5/2014. (mco)
- 12/9/14 Specialty Matched Consultant Advisory Panel review 11/24/14. No changes to Policy Statements. (sk)
- 7/1/15 Reference added. (sk)
- 12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)
- 1/27/17 References added. Specialty Matched Consultant Advisory Panel review 11/30/2016. Policy Guidelines updated. (sk)
- 9/15/17 Reference added. (sk)
- 12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)
- 10/12/18 Reference added. (sk)
- 12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)

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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.