



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

## Medical Policy

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

### Table of Contents

- [Policy: Commercial](#)
- [Coding Information](#)
- [Information Pertaining to All Policies](#)
- [Policy: Medicare](#)
- [Description](#)
- [References](#)
- [Authorization Information](#)
- [Policy History](#)

### Policy Number: 470

BCBSA Reference Number: 1.01.17

NCD/LCD: National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)

### Related Policies

- Sacral nerve neuromodulation/stimulation, #[153](#)
- Posterior Tibial Nerve Stimulation for Voiding Dysfunction, #[583](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for urinary incontinence is [INVESTIGATIONAL](#).

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for fecal incontinence is [INVESTIGATIONAL](#).

#### Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

BCBSMA covers pelvic floor electrical stimulation with a non-implantable stimulator for the following indication for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:

- For the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

Medical necessity criteria and coding guidance can be found through the link below.

[National Coverage Determinations \(NCDs\)](#)

National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)

**Note:** To review the specific NCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

## Prior Authorization Information

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The following HCPCS code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

### HCPCS Codes

HCPCS codes:	Code Description
E0740	Non-implanted pelvic floor electrical stimulator, complete system

## Description

### Pelvic Floor Stimulation

Pelvic floor stimulation (PFS) involves 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. Stimulation of the pudendal nerve to activate the pelvic floor musculature may improve urethral closure. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. Methods of electrical PFS have varied in location (eg, 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. Variations in the amplitude and frequency of the electrical pulse are used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the etiology of the incontinence (ie, 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 administered in the physician's office.

## Summary

### Description

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. Electrical stimulation of the pelvic floor is also proposed as a treatment of fecal incontinence.

### Summary of Evidence

For individuals who have urinary incontinence who receive electrical PFS, the evidence includes systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Findings from systematic reviews have not found that electrical PFS used to treat urinary incontinence in women consistently improves the net health outcome compared with placebo or other conservative treatments. 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. Among the RCTs that have evaluated electrical PFS as a treatment for fecal incontinence only 1 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 following factors: a low number of trials with short-term follow-up, methodologic limitations, as well as heterogeneity in patient populations, interventions, and outcomes reported. One RCT evaluating magnetic stimulation for treating men with postprostatectomy urinary incontinence 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.

## Policy History

Date	Action
10/2020	BCBSA National medical policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
1/2017	Clarified coding information for the 2017 code changes.
11/2016	New references added from BCBSA National medical policy.
8/2016	Clarified coding information.
6/2015	New references added from BCBSA National medical policy.
9/2014	BCBSA National medical policy review. New investigational indications described; title changed. Effective 9/1/2014.
5/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology.

	No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
3/2010	Updated to remove information related to biofeedback for urinary incontinence, as this will be separately addressed under Medical Policy, #173, effective 3/2010.
1/2010	BCBSA National medical policy review. Changes to policy statements.
6/2009	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2009	BCBSA National medical policy review. No changes to policy statements.
6/2008	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
11/2007	BCBSA National medical policy review. No changes to policy statements.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Pelvic floor electrical stimulation in the treatment of urinary incontinence in adults. TEC Assessments. 2000;Volume 15:Tab 2.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Magnetic stimulation in the treatment of urinary incontinence in adults. TEC Assessments. 2000;Volume 15:Tab 8.
3. Gorina Y, Schappert S, Bercovitz A, et al. Prevalence of incontinence among older americans. Vital Health Stat 3. Jun 2014; (36): 1-33. PMID 24964267
4. Markland AD, Goode PS, Redden DT, et al. Prevalence of urinary incontinence in men: results from the national health and nutrition examination survey. J Urol. Sep 2010; 184(3): 1022-7. PMID 20643440
5. Abdelbary AM, El-Dessoukey AA, Massoud AM, et al. Combined Vaginal Pelvic Floor Electrical Stimulation (PFS) and Local Vaginal Estrogen for Treatment of Overactive Bladder (OAB) in Perimenopausal Females. Randomized Controlled Trial (RCT). Urology. Sep 2015; 86(3): 482-6. PMID 26135813
6. Stewart F, Berghmans B, Bo K, et al. Electrical stimulation with non-implanted devices for stress urinary incontinence in women. Cochrane Database Syst Rev. Dec 22 2017; 12: CD012390. PMID 29271482
7. Shamliyan T, Wyman J, Kane R. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness (Comparative Effectiveness Review 36). Rockville, MD: Agency for Healthcare Research and Quality; 2012.
8. Moroni RM, Magnani PS, Haddad JM, et al. Conservative Treatment of Stress Urinary Incontinence: A Systematic Review with Meta-analysis of Randomized Controlled Trials. Rev Bras Ginecol Obstet. Feb 2016; 38(2): 97-111. PMID 26883864
9. Berghmans B, Hendriks E, Bernards A, et al. Electrical stimulation with non-implanted electrodes for urinary incontinence in men. Cochrane Database Syst Rev. Jun 06 2013; (6): CD001202. PMID 23740763
10. Zhu YP, Yao XD, Zhang SL, et al. Pelvic floor electrical stimulation for postprostatectomy urinary incontinence: a meta-analysis. Urology. Mar 2012; 79(3): 552-5. PMID 22386394

11. Goode PS, Burgio KL, Johnson TM, et al. Behavioral therapy with or without biofeedback and pelvic floor electrical stimulation for persistent postprostatectomy incontinence: a randomized controlled trial. *JAMA*. Jan 12 2011; 305(2): 151-9. PMID 21224456
12. Yamanishi T, Mizuno T, Watanabe M, et al. Randomized, placebo controlled study of electrical stimulation with pelvic floor muscle training for severe urinary incontinence after radical prostatectomy. *J Urol*. Nov 2010; 184(5): 2007-12. PMID 20850831
13. Cohen-Zubary N, Gingold-Belfer R, Lambort I, et al. Home electrical stimulation for women with fecal incontinence: a preliminary randomized controlled trial. *Int J Colorectal Dis*. Apr 2015; 30(4): 521-8. PMID 25619464
14. Norton C, Gibbs A, Kamm MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. *Dis Colon Rectum*. Feb 2006; 49(2): 190-6. PMID 16362803
15. 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*. Nov 2013; 28(11): 1567-77. PMID 23900652
16. Schwandner T, Konig IR, Heimerl T, et al. Triple target treatment (3T) is more effective than biofeedback alone for anal incontinence: the 3T-AI study. *Dis Colon Rectum*. Jul 2010; 53(7): 1007-16. PMID 20551752
17. Schwandner T, Hemmelmann C, Heimerl T, et al. Triple-target treatment versus low-frequency electrostimulation for anal incontinence: a randomized, controlled trial. *Dtsch Arztebl Int*. Sep 2011; 108(39): 653-60. PMID 22013492
18. Hosker G, Cody JD, Norton CC. Electrical stimulation for faecal incontinence in adults. *Cochrane Database Syst Rev*. Jul 18 2007; (3): CD001310. PMID 17636665
19. Lim R, Lee SW, Tan PY, et al. Efficacy of electromagnetic therapy for urinary incontinence: A systematic review. *Neurourol Urodyn*. Nov 2015; 34(8): 713-22. PMID 25251335
20. Yamanishi T, Homma Y, Nishizawa O, et al. Multicenter, randomized, sham-controlled study on the efficacy of magnetic stimulation for women with urgency urinary incontinence. *Int J Urol*. Apr 2014; 21(4): 395-400. PMID 24118165
21. 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*. May 2009; 103(10): 1386-90. PMID 19154474
22. Yokoyama T, Nishiguchi J, Watanabe T, et al. Comparative study of effects of extracorporeal magnetic innervation versus electrical stimulation for urinary incontinence after radical prostatectomy. *Urology*. Feb 2004; 63(2): 264-7. PMID 14972468
23. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults: AUA/SUFU Guideline. 2014; [https://www.auanet.org/guidelines/overactive-bladder-\(oab\)-\(aua/sufu-guideline-2012-amended-2014\)](https://www.auanet.org/guidelines/overactive-bladder-(oab)-(aua/sufu-guideline-2012-amended-2014)). Accessed August 27, 2019
24. National Institute for Health and Care Excellence (NICE) Guideline. Urinary Incontinence and Pelvic Organ Prolapse in Women: Management. NICE Guideline. 2019. Accessed June 22, 2020. <https://www.nice.org.uk/guidance/ng123>
25. National Institute for Health and Care Excellence (NICE). Faecal incontinence in adults: management [CG49]. 2007; <https://www.nice.org.uk/guidance/cg49>. Accessed June 22, 2020.
26. Qaseem A, Dallas P, Forcica MA, et al. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Sep 16 2014; 161(6): 429-40. PMID 25222388
27. Centers for Medicare & Medicaid Services (CMS). CMS Manual System: Pub 100-03 Medicare National Coverage Determinations; Transmittal 48. 2006; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=231&ncdver=2&NCAId=61&TAId=10&SearchType=Advanced&CoverageSelection=Both&NCSselection=NCA%257CCAL%257CNCD%257CMEDCAC%257CTA%257CMCD&ArticleType=Ed%257CKey%257CSAD%257CFAQ&PolicyType=Final&s=All&Keyword=Incontinence&KeywordLookup=Title&KeywordSearchType=Exact&CptHcpcsCode=E0740&kq=true&bc=IAAACAAQAAA&>. Accessed June 2020.