



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 BlueSM and Medicare PPO BlueSM 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.

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

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=231&ncdver=2&DocID=230.8&SearchType=Advanced&bc=IAAABAAAA&>

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 not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

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

INCONTINENCE

Incontinence, especially urinary, is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence and 17% issues with fecal incontinence.¹

Treatment

Nonsurgical treatment options for incontinence may include pharmacologic therapy, pelvic floor muscle exercises, bowel or bladder training exercises, electrical stimulation, and neuromodulation.

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

For individuals who have urinary 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. Findings from multiple RCTs 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. Meta-analyses of these RCTs have also reported inconsistent 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. 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
10/2018	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. 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
2. 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.
3. 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.
4. Imamura M, Abrams P, Bain C, et al. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. *Health Technol Assess*. Aug 2010;14(40):1-188, iii-iv. PMID 20738930
5. 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.
6. 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
7. Goode PS, Burgio KL, Locher JL, et al. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. *Jama*. Jul 16 2003;290(3):345-352. PMID 12865375
8. Castro RA, Arruda RM, Zanetti MR, et al. Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence. *Clinics (Sao Paulo)*. Aug 2008;63(4):465-472. PMID 18719756
9. 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):482-486. PMID 26135813
10. Berghmans B, Hendriks E, Bernards A, et al. Electrical stimulation with non-implanted electrodes for urinary incontinence in men. *Cochrane Database Syst Rev*. Jun 6 2013;6(6):CD001202. PMID 23740763
11. Zhu YP, Yao XD, Zhang SL, et al. Pelvic floor electrical stimulation for postprostatectomy urinary incontinence: a meta-analysis. *Urology*. Mar 2012;79(3):552-555. PMID 22386394
12. Goode PS, Burgio KL, Johnson TM, 2nd, 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):151-159. PMID 21224456

13. 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):2007-2012. PMID 20850831
14. 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):1567-1577. PMID 23900652
15. 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):1007-1016. PMID 20551752
16. 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):653-660. PMID 22013492
17. Hosker G, Cody JD, Norton CC. Electrical stimulation for faecal incontinence in adults. *Cochrane Database Syst Rev*. Jul 18 2007(3):CD001310. PMID 17636665
18. 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):521-528. PMID 25619464
19. Norton C, Gibbs A, Kamm MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. *Dis Colon Rectum*. Feb 2006;49(2):190-196. PMID 16362803
20. Lim R, Lee SW, Tan PY, et al. Efficacy of electromagnetic therapy for urinary incontinence: A systematic review. *Neurourol Urodyn*. Nov 2015;34(8):713-722. PMID 25251335
21. 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
22. Gillling 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):1386-1390. PMID 19154474
23. 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):264-267. PMID 14972468
24. 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 June 21, 2018.
25. Nambiar AK, Bosch R, Cruz F, et al. EAU guidelines on assessment and nonsurgical management of urinary incontinence. *Eur Urol*. Apr 2018;73(4):596-609. PMID 29398262
26. National Institute for Health and Care Excellence (NICE). Urinary Incontinence in Women: Management [CG171]. 2015; <https://www.nice.org.uk/guidance/cg171>. Accessed June 21, 2018.
27. National Institute for Health and Care Excellence (NICE). Faecal incontinence in adults: management [CG49]. 2007; <https://www.nice.org.uk/guidance/cg49>. Accessed June 21, 2018.
28. 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):429-440. PMID 25222388
29. 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&NCSelection=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=IAAAACAAQAAA&>. Accessed June 21, 2018.