

Medical Coverage Policy | Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence



EFFECTIVE DATE: 04|01|2001

POLICY LAST UPDATED: 08|16|2023

OVERVIEW

Pelvic floor stimulation 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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for Medicare Advantage Plans members only for the treatment of stress and/or urge urinary incontinence.

Pelvic floor electrical stimulation with a non-implantable stimulator for fecal incontinence is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products

Pelvic floor electrical or magnetic stimulation for urinary and fecal incontinence is not covered and considered contract exclusion.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable "Therapies, Acupuncture and Acupuncturist Services, and Biofeedback" benefits/coverage.

BACKGROUND

Commercial Products

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.

Urinary Incontinence

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 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.

Fecal Incontinence

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 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 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.

Medicare Advantage Plans

According to Medicare national coverage determination, non-implantable pelvic floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator. The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient's clinical diagnosis. Pelvic floor electrical stimulation with a non-implantable stimulator is covered 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. 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.

The document did not mention fecal incontinence. No studies were identified on magnetic PFS for treating fecal incontinence. Thus, electrical or magnetic PFS as a treatment of fecal incontinence is considered not medically necessary.

Regulatory Status

Several electrical stimulators have been cleared by the U.S. Food and Drug Administration (FDA). In 2006, the MyoTrac Infiniti™ (Thought Technology) 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. Predicate devices also used to treat urinary incontinence, including the Pathway™ CTS 2000 (Prometheus Group) and the InCare® PRS (Hollister). In 2011, the itouch Sure Pelvic Floor Exerciser (TensCare) was cleared for marketing.

In 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus) cleared through the FDA 510(k) 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 2014, the InTone® MV (InControl Medical), a nonimplantable device that provides electrical stimulation and/or biofeedback via manometry, was cleared by the FDA. The device is intended to treat male and female urinary and fecal incontinence.

FDA product code: KPI.

CODING

Medicare Advantage Plans for Urinary Incontinence

The following CPT code(s) are covered for Medicare Advantage Plans.

There are no specific CPT code(s) for this service and therefore the unlisted code should be used:

53899 Unlisted procedure, urinary system (to be used for pulsed magnetic stimulation for the treatment of incontinence)

The following code(s) are not specific to pelvic floor stimulation but will be covered when used for these services.

97014 Application of a modality to one or more areas; electrical stimulation (unattended)

97032 Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes

The following HCPCS code(s) is covered for Medicare Advantage Plans only.

E0740 Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

Commercial Products for Urinary Incontinence

The following CPT code(s) are not covered for Commercial Products.

There are no specific CPT codes for this service and therefore the unlisted code should be used:

53899 Unlisted procedure, urinary system (to be used for pulsed magnetic stimulation for the treatment of incontinence)

The following code(s) are not specific to pelvic floor stimulation and will be denied as non-covered for Commercial Products when used for these services:

97014 Application of a modality to one or more areas; electrical stimulation (unattended)

97032 Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes

The following HCPCS code(s) is not covered for Commercial Products.

E0740 Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

Medicare Advantage Plans and Commercial Products for Fecal Incontinence

There are no specific CPT code(s) for this service. Therefore, an unlisted code should be used.

RELATED POLICIES

Biofeedback

Unlisted Procedures

PUBLISHED

Provider Update, October 2023

Provider Update, January 2023

Provider Update, October 2021

Provider Update, November 2020

Provider Update, January 2020

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. 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
3. 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
4. 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.
5. Leonardo K, Seno DH, Mirza H, et al. Biofeedback-assisted pelvic floor muscle training and pelvic electrical stimulation in women with overactive bladder: A systematic review and meta-analysis of randomized controlled trials. *Neurourol Urodyn*. Jun 10 2022. PMID 35686543
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. Sciarra A, Viscuso P, Arditi A, et al. A biofeedback-guided programme or pelvic floor muscle electric stimulation can improve early recovery of urinary continence after radical prostatectomy: A meta-analysis and systematic review. *Int J Clin Pract*. Oct 2021; 75(10): e14208. PMID 33811418
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 06 2013; (6): CD001202. PMID 23740763
11. Zhu YP, Yao XD, Zhang SL, et al. Pelvic floor electrical stimulation for postprostatectomy urinary incontinence: ameta-analysis. *Urology*. Mar 2012; 79(3): 552-5. PMID 22386394
12. 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
- 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):2007-12. PMID 20850831

14. 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
15. 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
16. 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
17. 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
18. 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
19. Hosker G, Cody JD, Norton CC. Electrical stimulation for faecal incontinence in adults. *Cochrane Database Syst Rev.* Jul 18 2007; (3): CD001310. PMID 17636665
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): 713-22. 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. 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
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): 264-7. PMID 14972468
24. Lightner DJ, Gomelsky A, Souter L, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. *J Urol.* Sep 2019; 202(3): 558-563. PMID 31039103
25. Sandhu JS, Breyer B, Comiter C, et al. Incontinence after Prostate Treatment: AUA/SUFU Guideline. *J Urol.* Aug 2019; 202(2): 369-378. PMID 31059663
26. National Institute for Health and Care Excellence (NICE) Guideline. Urinary Incontinence and Pelvic Organ Prolapse in Women: Management. NICE Guideline. 2019. <https://www.nice.org.uk/guidance/ng123>. Accessed June 16, 2022.
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 15, 2022.
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): 429-40. PMID 25222388
29. Paquette IM, Varma MG, Kaiser AM, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence. *Dis Colon Rectum.* Jul 2015; 58(7): 623-36. PMID 26200676
30. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. *Am J Gastroenterol.* Oct 01 2021; 116(10): 1987-2008. PMID 34618700
31. 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>. Accessed June 16, 2022.

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