BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.17 Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

Annual Effective Policy Date: January 1, 2024

Original Policy Date: December 2012

Related Policies:

7.01.106 - Percutaneous and Subcutaneous Tibial Nerve Stimulation

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

Description

Description

Pelvic floor stimulation is proposed as a nonsurgical treatment option for women and men with urinary or fecal incontinence. This approach involves either electrical stimulation of pelvic floor musculature or extracorporeal pulsed magnetic stimulation.

OBJECTIVE

The objective of this evidence review is to determine whether electrical or magnetic pelvic floor stimulation improves the net health outcome in individuals with urinary or fecal incontinence compared with behavioral therapies and/or medication therapy.

POLICY STATEMENT

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for urinary incontinence is considered **not medically necessary**.

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for fecal incontinence is considered **not medically necessary**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 are 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) was 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.

RATIONALE

Summary of Evidence

For individuals who have urinary incontinence who receive electrical pelvic floor stimulation (PFS) , the evidence includes systematic reviews of randomized controlled trials (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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

For individuals who have fecal incontinence who receive magnetic PFS, no relevant evidence was identified. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2021, the American College of Gastroenterology issued guidelines on the management of benign anorectal disorders.[24,] In the section on fecal incontinence, pelvic floor stimulation (PFS) is not mentioned as a treatment option.

American Society of Colon and Rectal Surgeons

In 2023, the American Society of Colon and Rectal Surgeons updated an evidence-based guideline using GRADE methodology on treatment of fecal incontinence.[25,] Dietary interventions and medical management are considered first-line treatments; PFS was not included in the recommendations.

American Urological Association et al

In 2019, the American Urological Association (AUA) published guidelines on the diagnosis and management of overactive bladder.[26,] Neither electrical nor magnetic PFS were mentioned as recommended first-, second-, or third-line treatment options.

Joint guidelines issued in 2019 by the AUA and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) on management of post-prostatectomy urinary incontinence do not specifically address electrical or magnetic PFS as treatment options. Pelvic floor muscle training/exercise is recommended as first-line treatment for post-prostatectomy incontinence.[27,]

National Institute for Health and Care Excellence

In 2019, the NICE issued guidance on the management of urinary incontinence in women.[28,] The NICE stated that electrical stimulation, alone or as an adjunct to pelvic floor muscle training, should not be routinely used to treat women with overactive bladder. The NICE guidance further stated: "electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy." Magnetic PFS is not mentioned.

In 2007, the NICE issued guidance on the management of fecal incontinence in adults.[29,] This guidance was last reviewed by NICE in 2018. The document stated that the evidence on electrical stimulation for treatment of fecal incontinence was inconclusive. The NICE recommended that patients who continue to have episodes of fecal incontinence after initial treatment be considered for specialized management, which may include electrical PFS. Magnetic PFS is not mentioned.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The national coverage determination for Non-Implantable Pelvic Floor Electrical Stimulator (230.8) stated: "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."[30,] The effective date was June 19, 2006. The document did not mention fecal incontinence.

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. Aug 2022; 41(6): 1258-1269. PMID 35686543
6. Stewart F, Berghmans B, B K, et al. Electrical stimulation with non-implanted devices for stress urinary incontinence in women. Cochrane Database Syst Rev. Dec 22 2017; 12(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: a meta-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, Knig 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; 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. 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
25. Bordeianou LG, Thorsen AJ, Keller DS, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Fecal Incontinence. Dis Colon Rectum. May 01 2023; 66(5): 647-661. PMID 36799739
26. 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
27. 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
28. 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 22, 2023.

29. 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, 2023.
30. 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 22, 2023.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	
June 2013	Replace policy	Policy updated with literature review, References 8 and 15 added, others renumbered or removed. No change to policy statement.
June 2014	Replace policy	Policy updated with literature review. References 4, 8, 13-18 and 24 added; other references renumbered or removed. "And fecal€š added to policy title. Statement added that electrical or magnetic stimulation of the pelvic floor muscles as a treatment for fecal incontinence is considered not medically necessary.
June 2015	Replace policy	Policy updated with literature review. References 17, 24, and 26 added. Policy statements unchanged.
March 2017	Replace policy	Policy updated with literature review; references 5, 8, 19, and 23 added. Policy statements changed from not medically necessary to investigational.
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; no references added. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through June 4, 2018; references 1 and 25 added. Policy statements unchanged except "investigational€š change to "not medically necessary€š for urinary incontinence due to FDA PMA device.
December 2019	Replace policy	Policy updated with literature review through June 10, 2019; references added. Policy statements unchanged except "not medically necessary" changed to "investigational" and NeoControl Pelvic Floor Therapy System FDA information corrected from PMA to 510(k).
December 2020	Replace policy	Policy updated with literature review through June 17, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through July 1, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through June 16, 2022; references added. Policy statements unchanged.
December 2023	Replace policy	Policy updated with literature review through June 17, 2023; reference added. Policy statements unchanged except "investigational" changed to "not medically necessary" for treatment of urinary and fecal incontinence due to FDA PMA 510K process.