



FEP Medical Policy Manual

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

Effective Policy Date: January 1, 2021

Related Policies:

7.01.106 - Percutaneous Tibial Nerve Stimulation

Original Policy Date: Decemer 2012

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

Description

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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.

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 **investigational**.

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

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 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. This product is being marketed in the United States as EmbaGYN (Everett Laboratories).

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.

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 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,

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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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Urological Association

In 2014, the American Urological Association published guidelines on the diagnosis and management of overactive bladder.²³ Neither electrical pelvic floor stimulation (PFS) nor magnetic PFS was mentioned as recommended first-, second-, or third-line treatment options.

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) issued guidance on the management of urinary incontinence in women.²⁴ 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.²⁵ (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.

American College of Physicians

The American College of Physicians (2014) issued guidelines on the nonsurgical management of urinary incontinence.²⁶ Electrical PFS and magnetic PFS were not discussed.

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

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patients who have failed a documented trial of pelvic muscle exercise (PME) training."²⁷ The effective date was June 19, 2006. The document did not mention fecal incontinence.

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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" 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 except "not medically necessary" corrected to "investigational"
December 2018	Replace policy	Policy updated with literature review through June 4, 2018; references 1 and 25 added. Policy statements unchanged except "investigational" change to "not medically necessary" for urinary incontinence due to FDA PMA device.

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Date	Action	Description
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.

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