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

EFFECTIVE DATE:04|01|2001
POLICY LAST UPDATED: 08|16|2021

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable.

PRIOR AUTHORIZATION
Prior authorization review is not required.

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 medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

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. 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.

CODING

Advantage Plans for Urinary Incontinence
The following 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 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 and therefore the unlisted code should be used

RELATED POLICIES
Biofeedback
Unlisted Procedures

PUBLISHED
Provider Update, October 2021
Provider Update, November 2020
Provider Update, January 2020
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