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

EFFECTIVE DATE:04|01|2001
POLICY LAST UPDATED: 12|03|2019

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
BlueCHiP for Medicare
Pelvic floor electrical stimulation with a non-implantable stimulator is covered for BlueCHiP for Medicare 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 BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial Products
Pelvic floor electrical 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
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. The intent of the intervention is to stimulate the pudendal nerve to activate the pelvic floor musculature; it is thought that activation of these muscles will lead to improved urethral closure. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. The 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. Variation in the amplitude and frequency of the electrical pulse is used to mimic and stimulate the different physiologic mechanisms of
the voiding response, depending on the type of etiology of 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 delivered in the physician's office.

PFS was first proposed as a treatment for urinary incontinence and later also proposed as a treatment for fecal incontinence. Incontinence, especially urinary, is a common condition and can have a substantial impact on quality of life. Nonsurgical treatment options for incontinence may include pharmacologic therapy, pelvic floor muscle exercises, bowel or bladder training exercises, electrical stimulation, and neuromodulation.

Urinary Incontinence
Findings from multiple randomized controlled trials (RCTs) have not found that electrical PFS used to treat urinary incontinence in women consistently improved the net health outcome compared with placebo or other conservative treatments. Meta-analyses of these RCTs have had mixed findings. There is insufficient evidence on the efficacy of electrical PFS in the treatment of postprostatectomy incontinence
in men, and on the efficacy of magnetic PFS for treating urinary incontinence in men or women.
Thus,electrical or magnetic PFS as a treatment of urinary incontinence is considered not medically necessary.
Fecal Incontinence
Several RCTs have been published evaluating electrical PFS used to treat fecal incontinence. Only 1 trial was sham-controlled, and this did not find that electrical stimulation improved the net health outcome. Systematic reviews of RCTs have not found that electrical stimulation was superior to control interventions for treating 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.

Blue CHiP for Medicare
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

BlueCHiP Medicare for Urinary Incontinence
The following codes are covered for BlueCHiP for Medicare.
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 codes 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 is covered for BlueCHiP for Medicare only.
E0740 Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

Commercial for Urinary Incontinence
The following codes are not covered for Commercial.
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 codes are not specific to pelvic floor stimulation and will be denied as non-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 is not covered for Commercial.
E0740 Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

Blue CHip for Medicare and Commercial for fecal incontinence
There are no specific CPT codes for this service and therefore the unlisted code should be used

RELATED POLICIES

Biofeedback

PUBLISHED

Provider Update, January 2020
Provider Update, May 2018
Provider Update, April, 2017
Provider Update, September 2016
Provider Update, December 2015
Provider Update, October 2014

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