

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



EFFECTIVE DATE: 04|01|2001

POLICY LAST UPDATED: 10|6|2015

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 is not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

Commercial Products

Pelvic floor electrical stimulation for urinary and fecal incontinence is not covered and considered a 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

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 (e.g., 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, i.e., 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.

BlueCHiP 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.

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

The following codes are not specific to pelvic floor stimulation, but will be covered when used for these services:

97014

97032

The following HCPCS code is **covered for BlueCHiP for Medicare only:**

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

Commercial Products for Urinary Incontinence

The following codes are not covered for Commercial products:

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

53899

The following codes are not specific to pelvic floor stimulation and will be denied as non-covered when used for these services:

97014

97032

The following HCPCS code is **not covered for Commercial products:**

E0740

BlueCHiP for Medicare and Commercial Products 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, December 2015

Provider Update, October 2014

Provider Update, August 2013

Provider Update, January 2012

Provider Update, December 2010

Provider Update, October 2009

Provider Update, October 2008

Policy Update, January 2008

REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)
2. Imamura M, Abrams P, Bain C et al. Systematic review and economic modeling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. Health Technology Assessment 2010; Volume 14, No. 40. Available online at: <http://www.hta.ac.uk/1612>. Last accessed March, 2014.
3. Shamliyan T, Wyman J, Kane R. Agency for Healthcare Research and Quality (AHRQ): Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness. 2012.

Available online at: <http://effectivehealthcare.ahrq.gov/ehc/products/169/834/urinary-incontinence-treatment-report-130909.pdf>. Last accessed March, 2014.

4. Goode PS, Burgio KL, Locher JL et al. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. *Jama* 2003; 290(3):345-52.
5. Wang AC, Wang YY, Chen MC. Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder. *Urology* 2004; 63(1):61-6.
6. Castro RA, Arruda RM, Zanetti MR et al. Single-blind randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones and no active treatment in the management of stress urinary incontinence. *Clinics (Sao Paulo)* 2008; 63(4):465-72.

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