Protocol

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

(10117)

Medical Benefit		**Effective Date**: 07/01/14	**Next Review Date**: 05/21
Preauthorization	No	**Review Dates**: 01/08, 11/08, 09/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With urinary incontinence	Interventions of interest are: • Electrical pelvic floor stimulation	Comparators of interest are: • Behavioral therapy (e.g., fluid intake, pelvic floor muscle training) • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With fecal incontinence	Interventions of interest are: • Electrical pelvic floor stimulation	Comparators of interest are: • Behavioral therapy (e.g., fluid intake, pelvic floor muscle training) • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With urinary incontinence	Interventions of interest are: • Magnetic pelvic floor stimulation	Comparators of interest are: • Behavioral therapy (e.g., diet, pelvic floor muscle training) • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With fecal incontinence	Interventions of interest are: • Magnetic pelvic floor stimulation	Comparators of interest are: • Behavioral therapy (e.g., diet, pelvic floor muscle training) • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity

DESCRIPTION

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.

SUMMARY OF EVIDENCE

For individuals who have urinary incontinence who receive electrical PFS, the evidence includes randomized

controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, change in disease status, quality of life (QOL), and treatment-related morbidity. Findings from multiple RCTs 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. Meta-analyses of these RCTs have also reported inconsistent findings. 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. The relevant outcomes are symptoms, change in disease status, QOL, 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 urinary incontinence who receive magnetic PFS, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms, change in disease status, QOL, 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.

For individuals who have fecal incontinence who receive magnetic PFS, the evidence includes no RCTs or non-RCTs. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

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

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

MEDICARE ADVANTAGE

Pelvic floor electrical stimulation with a non-implantable stimulator is **medically necessary** 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 four weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

BACKGROUND

PELVIC FLOOR STIMULATION

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 (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. 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 (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 administered in the physician's office.

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.

RELATED PROTOCOLS

Percutaneous Tibial Nerve Stimulation

Sacral Nerve Neuromodulation/Stimulation

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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