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Pelvic Floor Stimulation (PFS) as a Treatment of Urinary or Fecal Incontinence

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Related Policies (if applicable)
None

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Coverage

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation, or PFS) **is considered experimental, investigational and/or unproven** as a treatment for urinary or fecal incontinence**.**

Policy Guidelines

None.

Description

Pelvic floor stimulation (PFS) is proposed as a nonsurgical treatment option for women and men with urinary or fecal incontinence. This approach involves either electrical stimulation of pelvic floor musculature or extracorporeal pulsed magnetic stimulation.

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 Apex®M (now Apex®; InControl Medical) nonimplanted electrical stimulators for treating urinary incontinence were cleared for marketing by the FDA through the 510(k) process. Predicate devices are 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.

In 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus) was 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

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Electrical Pelvic Floor Stimulation for Urinary Incontinence

Clinical Context and Therapy Purpose

The purpose of pelvic floor stimulation (PFS) in individuals who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with urinary incontinence. Types of urinary incontinence include stress incontinence, urgency incontinence, and mixed (both stress and urgency).

Urinary incontinence is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence. (1) Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history.

Urinary incontinence is less common in men, with estimates ranging from 11% to 16% in men greater than 65 years. (2) Factors that increase a man's risk include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Interventions
The therapy being considered is electrical PFS for urinary incontinence. In an electrical PFS procedure, a probe delivers electrical pulses to stimulate the pudendal nerve, which activates the pelvic floor musculature. Activation of this musculature is believed to improve urethral closure.

Comparators
The following therapies are currently being used to make decisions about urinary incontinence: magnetic PFS or neuromodulation, behavioral therapies (e.g., monitoring fluid intake, bladder, and pelvic floor muscle training, diet), and medications.

Outcomes
The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Short-term results can be measured at 6 months. (3) Longer-term follow-up may be necessary to determine if treatment has durable effects.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

<u>Urinary Incontinence in Women</u>
Systematic Reviews
Several systematic reviews of the literature with pooled study findings have been published.

Leonardo et al. (2022) published a systematic review and meta-analysis of 8 RCTs (N=562) which evaluated the comparative effectiveness of biofeedback-assisted pelvic floor muscle training (PFMT) versus PFS versus a control group (PFMT alone, bladder training, or lifestyle recommendations only) in women with overactive bladder. (4) Outcomes assessed included quality of life, number of episodes of incontinence, and number of patients who improved or were cured. The PFS group exhibited significant differences in quality of life (mean difference, 7.41; 95% confidence interval [CI], 7.90 to 12.92; p=.008), episodes of incontinence (mean difference, -1.33; 95% CI, -2.50 to -0.17; p=.02), and the number of patients who improved or were cured (risk ratio, 1.46; 95% CI, 1.14 to 1.87; p=.003) compared to the control group. The biofeedback-assisted PFMT group did not have significant differences in any of these outcomes compared to the control group. Limitations of the study include high heterogeneity for some analyses and differences in the qualitative and quantitative assessments utilized in the included RCTs which limits the direct comparability among the studies.

A 2017 Cochrane review evaluated the effect of PFS on self-reported incontinence. (5) The review found no difference between PFS and PFMT in the likelihood of cure of stress incontinence at 6 months based on the results of 4 RCTs (N=143; relative risk [RR], 0.51; 95% CI, 0.15 to 1.63). There was also no difference between groups in adverse event rates based on an imprecise estimate (RR, 5.00; 95% CI, 0.25 to 99). Quality of life was not reported. The same review included studies comparing PFS + PFMT versus PFMT alone, finding no difference between groups in incontinence rates based on 3 trials (n=99; RR, 0.76; 95% CI, 0.38 to 1.52). The review found a small benefit of PFS + PFMT on incontinence-related quality of life when compared with PFMT alone (standard mean difference, -0.77; 95% CI, -1.11 to -0.42). The review deemed the evidence for PFS alone or in combination with PFMT versus PFMT alone inconclusive for incontinence and quality of life outcomes.

An Agency for Healthcare Research and Quality comparative effectiveness review prepared by Shamliyan et al. (2012) identified 9 RCTs evaluating electrical intravaginal stimulation in women with urgency, stress, or mixed incontinence. (6) Eight of the 9 studies were published in 2000 or earlier; nearly all used a sham treatment as the control. A pooled analysis of continence rates in 8 RCTs comparing electrical PFS with no active treatment yielded an RR of 2.86 (95% CI, 1.57 to 5.23). A pooled analysis of the reduction in incontinence symptoms yielded an RR of 2.01 (95% CI, 1.28 to 3.15). Reviewers concluded that a high level of evidence suggested electrical PFS is associated with increased continence rates, and that such stimulation improved urinary incontinence.

Moroni et al. (2016) published a systematic review of conservative treatment for stress urinary incontinence. (7) Five trials (N=221 women) were identified comparing intravaginal electrical PFS with control. There were insufficient data on cure rates (e.g., continence rates). A pooled analysis of 4 studies reporting urine quantity with a pad weight test found a significantly greater reduction in pad weight in the treatment versus control groups (mean difference, -9.15; 95% CI, -17.22 to -1.08). A pooled analysis of 2 studies found significantly greater improvement in the incontinence-specific quality of life in the electrical PFS group than in the control group (mean difference, -1.44; 95% CI, -1.94 to -0.95). Three studies were included in a pooled analysis of a number of incontinence episodes; the findings were not reported. Reviewers stated that, among all conservative treatments assessed, evidence was strongest in support of PFS, with or without biofeedback, for treatment of stress urinary incontinence.

<u>Men with Postprostatectomy Urinary Incontinence</u>

Systematic Reviews

Sciarra et al. (2021) conducted meta-analyses comparing the effect of PFS with PFMT and biofeedback on urinary incontinence in men following radical prostatectomy. (8) The review included 5 RCTs of PFS, the most recent of which was published in 2018. PFS devices, frequency, and duration varied among the trials. At 3 months, the effect size for continence recovery (based on pad-free event rate) was 0.57 (95% CI, 0.46 to 0.69) for PFS, 0.40 (95% CI, 0.30 to 0.49) for PFMT, and 0.54 (95% CI, 0.32 to 0.75) for biofeedback (p=.01 for both PFS and biofeedback vs. PFMT). At 6 and 12 months, PFS effect sizes were 0.78 (95% CI, 0.59 to 0.98) and 0.82 (95% CI, 0.65 to 0.99), respectively, and there was no longer a statistically significant difference between any treatment group and rate of continence recovery.

A Cochrane review by Berghmans et al. (2013) identified 6 RCTs on electrical PFS with nonimplanted electrodes for postprostatectomy urinary incontinence in men. (9) The trials varied by intervention used, study protocols, study populations, and outcome measures. In a pooled analysis of 4 RCTs comparing the combination of electrical stimulation and pelvic floor muscle exercises with pelvic floor muscle exercises alone, there was no statistically significant difference between groups in the proportion of men with urinary incontinence at 3 months (RR, 0.93; 95% CI, 0.82 to 1.06). Findings from studies evaluating electrical PFS alone were not pooled. A 2023 Cochrane review on conservative interventions for managing urinary incontinence after prostate surgery found no studies on electrical or magnetic stimulation compared with no treatment, sham, or verbal/written instructions that reported on key outcomes. (10)

Zhu et al. (2012) conducted a meta-analysis and reported similar findings for electrical PFS to treat postprostatectomy urinary incontinence. (11) Reviewers identified 4 RCTs (N=210 men) that provided sufficient data on clinical outcomes. A pooled analysis of data from 3 trials did not find a statistically significant benefit of electrical PFS on continence levels compared with controls within 3 months of prostatectomy (RR, 1.21; 95% CI, 0.96 to 1.54). Similarly, a pooled analysis of data from all 4 trials did not show a statistically significant benefit of electrical PFS on continence levels 6 to 12 months after prostatectomy (RR, 1.03; 95% CI, 0.88 to 1.20).

Randomized Controlled Trials

Representative trials of men with postprostatectomy urinary incontinence include the RCT by Goode et al. (2011) comparing behavioral therapy alone with behavioral therapy plus biofeedback and electrical PFS. (12) The trial included 208 men with urinary incontinence persisting at least 1 year after radical prostatectomy. Men with preprostatectomy incontinence were excluded. Participants were randomized to 1 of 3 groups: 8 weeks of behavioral therapy (PFMT plus bladder control exercises; n=70), behavioral therapy plus biofeedback and electrical stimulation (n=70), and a delayed-treatment control group (n=68). The biofeedback plus electrical stimulation intervention (called "behavior-plus") consisted of in-office electrical stimulation with biofeedback using an anal probe and daily home electrical PFS. After 8 weeks, patients in the 2 active treatment groups were given instructions for a maintenance program of pelvic floor exercises and fluid control; they were then given follow-up at 6 and 12 months. The primary efficacy outcome was a reduction in the number of incontinent episodes at 8 weeks, as measured by a 7-day bladder diary. A total of 176 (85%) of 208 randomized men completed the 8 weeks of treatment. In an intention-to-treat analysis of the primary outcome, the mean reduction in incontinent episodes was 55% (28 to 13 episodes per week) in the behavioral therapy group, 51% (from 26 to 12 episodes per week) in the behavior-plus group, and 24% (from 25 to 20 episodes per week) in the control group. The overall difference between groups was statistically significant (p=.001), but the behavior-plus intervention did not result in a significantly better outcome than behavioral therapy alone. Findings were similar for other outcomes. For example, at the end of 8 weeks, there was a significantly higher rate of complete continence in the active treatment groups (11/70 [16%] in the behavior group vs. 12/70 [17%] in the behavior-plus group) than in the control group (4/68 [6%]); however, the group receiving biofeedback and electrical PFS did not have a significantly higher continence rate than the group receiving behavioral therapy alone. The trial did not isolate the effect of electrical PFS, and the combined behavior-plus intervention did not result in better outcomes than behavioral therapy alone.

Yamanishi et al. (2010) published findings of an RCT comparing electrical stimulation with a sham control group. (13) This trial, conducted in Japan, was double-blinded; in it, 56 men with severe postprostatectomy urinary incontinence were randomized to active (n=26) or sham (n=30) electrical PFS. All the men performed PFMT. Active or sham electrical PFS was performed until incontinence was resolved or until the end of the study at 12 months. Forty-seven patients (22 in the active stimulation group, 25 in the sham group) completed the trial. The continence rate (defined as loss of ≤8 grams of urine during a 24-hour pad test) was the primary efficacy outcome. There was a statistically higher rate of continence at 1, 3, and 6 months in the active stimulation group than in the sham group but the between-group difference was not statistically significant at 12 months. The numbers of men reported as continent in the active electrical PFS group were 8 (36%), 14 (63%), 18 (81%), and 19 (86%) at 1, 3, 6, and 12 months, respectively. Corresponding rates in the sham group were 1 (4%), 4 (16%), 11 (44%), and 17 (86%), respectively. Differences in the amount (number of grams) of daily leakage as measured by 24-hour pad tests differed significantly between groups at 1 month; however, the difference disappeared at the 12-month follow-up. For example, after 1 month, the mean amount of leakage was 210 grams in the active treatment group and 423 grams in the sham group (p>.05). Change in the amount of daily leakage from baseline differed significantly between groups at 1 month (-528 grams in the active treatment group vs. -257 grams in the sham group, p<.01) but not at the other follow-up time points.

<u>Section Summary: Electrical Pelvic Floor Stimulation for Urinary Incontinence</u>
A majority of RCTs on electrical PFS for treatment of women with urinary incontinence have been published before 2001. Meta-analyses of RCTs have had inconsistent findings on the impact of electrical intravaginal stimulation on urinary incontinence in women compared with sham treatment.

Individual RCTs have evaluated electrical PFS as a treatment of postprostatectomy urinary incontinence in men. These studies reported improvements in some outcomes with electrical PFS but also have limitations, such as failure to isolate the effect of electrical PFS, and/or failure to find a sham comparator or an accepted treatment comparator. Pooled analyses from 3 systematic reviews found inconsistent evidence on the effect of PFS on continence at 3 months (1 found significant benefit and 2 did not), and found no clear benefit of PFS at 6- and 12-month follow-up.

Electrical PFS for Fecal Incontinence

Clinical Context and Therapy Purpose

The purpose of PFS in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with fecal incontinence. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence. Risk factors for fecal incontinence are similar in men and women: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes.

Interventions

The therapy being considered is electrical PFS for fecal incontinence.

Comparators

The following therapies are currently being used to make decisions about fecal incontinence: nonsurgical treatment options and behavioral therapies. Nonsurgical treatment options for incontinence may include pharmacologic therapy, bowel training exercises, and magnetic stimulation. Behavioral therapies include pelvic floor muscle training and diet.

Outcomes

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Electrical PFS therapy generally continues for 6 to 8 weeks. (14, 15)

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

A systematic review by Vonthein et al. (2013) searched for studies on the impact of biofeedback and/or electrical PFS for treating fecal incontinence in adults. (16) They identified 13 RCTs that used 1 or both of these treatments and reported health outcomes (e.g., remission or response rates using validated scales). A pooled analysis of trial results did not find statistically significant differences in rates of remission when comparing electrical PFS with a control intervention (RR, 0.47; 95% CI, 0.13 to 1.72). A pooled analysis of studies comparing electrical PFS plus biofeedback with electrical PFS alone found a significantly higher rate of remission with the combination intervention (RR, 22.97; 95% CI, 1.81 to 291.69). The latter analysis focused on the efficacy of biofeedback and not electrical PFS. Additionally, the confidence interval was very wide, indicating an imprecise estimate of the treatment effect. The Vonthein et al. (2013) review included only 2 RCTs on electrical PFS (17, 18) that were published after a Cochrane review (below). These 2 trials included the combination of amplitude-modulated medium-frequency stimulation and biofeedback. Electrical PFS was not evaluated in the absence of biofeedback.

A Cochrane review by Hosker et al. (2007) identified 4 RCTs evaluating electrical stimulation as a treatment of fecal incontinence in adults. (19) One trial was sham-controlled, another compared electrical PFS with levatorplasty, and 2 used electrical PFS as an adjunct treatment. Reviewers did not pool study findings; they concluded that there is insufficient evidence to draw conclusions on the efficacy of electrical PFS for treating fecal incontinence.

Randomized Controlled Trials

An RCT by Cohen-Zubary et al. (2015) allocated 42 women with fecal incontinence to 6 weeks of electrical stimulation (n=22) or biofeedback training (n=20). (14) Biofeedback sessions were conducted in-clinic and electrical PFS sessions at home following an initial training in-clinic. Thirty-six (86%) women completed the trial and were included in the analysis; the analysis was not intention-to-treat. The trial's primary endpoints were improvements in frequency of fecal, urine, and gas incontinence, assessed using visual analog scale scores. There were no statistically significant differences between groups for the primary outcomes. The mean visual analog scale score (standard deviation [SD]) for solid stool incontinence at baseline in the stimulation group was 2.9 (2.8), which decreased to 0.9 (0.9) at follow-up. In the biofeedback group, the baseline visual analog scale score was 1.1 (2.1) and 0.3 (0.5) at follow-up. The between-group difference for this outcome was not statistically significant. For within-group changes, the electrical stimulation group improved significantly on solid stool incontinence-but not on liquid stool or gas incontinence and the biofeedback group did not improve significantly on any of the fecal incontinence outcomes.

Norton et al. (2006) in the U.K. published a sham-controlled randomized trial that included 90 adults with fecal incontinence. (15) Patients used a home electric PFS device for 8 weeks. Patients allocated to active treatment had the stimulation set at 35 Hz, with a 0.5-second ramped pulse. The sham stimulator looked identical, but stimulation was set at 1 Hz below the level tested for therapeutic effect. Patients were blinded to the treatment group; although nurses who trained patients on device use were not. The primary outcome was patient self-report of efficacy, using a rating scale ranging from -5 to +5 to indicate symptom change. Seventy (78%) of the 90 patients completed the trial. In an intention-to-treat analysis (assigning patients who dropped out a value of 0), there was no statistically significant difference between groups in patient ratings of symptom change. On a scale of -5 to +5, there was a median rating of 0 in each group (p=.92). In a completer analysis, the median change in symptoms was 2 in the active treatment group and 1 in the sham group (p=.74). Groups did not differ significantly on other secondary outcomes such as the frequency of urge or passive incontinence after treatment.

Section Summary: Electrical PFS for Fecal Incontinence

Several RCTs have evaluated electrical stimulation for treating fecal incontinence. Only 1 was sham-controlled, and it did not find that active stimulation produced better results than sham stimulation. Systematic reviews of RCTs have not found that electrical stimulation is superior to control interventions for treating fecal incontinence.

Magnetic PFS for Urinary Incontinence

Clinical Context and Therapy Purpose

The purpose of magnetic PFS in individuals who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with urinary incontinence. Types of urinary incontinence include stress incontinence, urgency incontinence, and mixed (both stress and urgency). Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history. Urinary incontinence is less common in men, with estimates ranging from 11% to 34% in men greater than 65 years. Factors that increase a man's risk include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Interventions

The therapy being considered is magnetic PFS for urinary incontinence. The mechanism of action of a magnetic PFS procedure is similar to the electrical procedure, though using magnetic pulses to activate the pelvic floor musculature. The magnetic pulses are delivered without a probe, with patients sitting fully clothed in a specialized chair with an embedded magnet.

Comparators

The following therapies are currently being used to make decisions about urinary incontinence: electrical PFS and behavioral therapies (e.g., monitoring fluid intake, pelvic floor muscle training, diet), and medications.

Outcomes

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Treatment is for approximately 8 weeks, and follow-up is generally up to 6 months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Women with Urinary Incontinence

Systematic Reviews

A systematic review of RCTs on magnetic stimulation for the treatment of urinary incontinence was published by Lim et al. (2015). (20) Reviewers identified 8 blinded, sham-controlled trials (N=484). Treatment protocols (e.g., frequency, duration of magnetic PFS) varied among trials. The primary outcome was cure rate; only 1 trial reported this outcome, so data were not pooled. A meta-analysis of 3 studies reporting improvements in the continence rates found significantly greater improvement in the treatment group than in the sham group (RR, 2.29; 95% CI, 1.60 to 3.29). Due to the variability across trials in types of incontinence treated and/or outcome reporting, data were not pooled for other outcomes. Reviewers noted that the evidence was limited by low-quality trials with short-term follow-up.

Randomized Controlled Trials

Yamanishi et al. (2014) published an industry-sponsored evaluation of magnetic PFS provided to women with urinary urgency using an armchair-type stimulator. (21) The device was produced by a Japanese company and does not have FDA approval. Patients received active (n=101) or sham (n=50) stimulation, 2 times a week for 6 weeks. The level of stimulation was tailored to each patient's maximum tolerable intensity; sham stimulation was set at a lower level than active treatment. Because noises differed between the 2 procedures, patients were isolated from the sounds to maintain blinding. Study personnel were not blinded. A total of 143 (95%) of 151 patients were included in the efficacy analysis. The primary endpoint was a change in the number of urinary incontinence episodes per week, as reported in a patient diary. The decrease in the weekly number (SD) of incontinence episodes was 13 (11) in the active treatment group compared with 9 (13) in the sham group (p=.038). Patients in the active stimulation group had significantly better results on some secondary outcomes (e.g., number of urgency episodes per 24 hours) but not others (e.g., number of voids per 24 hours).

A sham-controlled randomized trial evaluating magnetic PFS using the NeoControl chair did not find evidence that PFS improved outcomes. In this trial by Gilling et al. (2009) in New Zealand, sham treatment involved inserting a thin aluminum plate in the chair to prevent penetration of the magnetic field. (22) The trial included 70 women, 35 in each group, with stress or mixed urinary incontinence. Both groups received 3 treatment sessions per week for 6 weeks. There was no significant difference between the active and sham treatment groups for the primary outcome measure, change from baseline in the 20-minute pad test result to 8 weeks after the start of treatment (2 weeks after finishing treatment). At 8 weeks, the mean change in the 20-minute pad test was 20.1 mL in the treatment group and 7.5 mL in the control group. The groups also did not differ significantly in the 20-minute pad weight or quality of life measure at the 6-month follow-up. Data from 29 (83%) women in the active treatment group and 26 (74%) women in the sham group were available at 6 months; all participants appear to be included in the 8-week outcomes analysis.

Lim et al. (2017) randomized 120 women with stress urinary incontinence to treatment with magnetic PFS (QRS®-1010 PelviCenter) or sham treatment. (23) Patients received 2 sessions per week for 8 weeks (16 sessions). Patients who were unsatisfied after 2 months were allowed 16 additional active sessions in an open-label phase. All participating study centers were located in Malaysia. The primary endpoint of response was defined as a 5-point reduction on the International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form (ICIQ-UI SF). A total of 45 (75.0%) patients responded at 2 months in the active treatment group compared with 13 (21.7%) patients in the sham group (RR, 3.46; 95% CI, 2.09 to 5.72; p<.001). At long-term follow-up (14 months), the patients who received 16 or more active sessions had improved response rates than those who received none (response rates of 68.3% to 75.0% vs. 21.1%). The study is limited by the small sample size and the limited demographic heterogeneity.

Men with Postprostatectomy Urinary Incontinence

Systematic Review

A 2023 Cochrane review on conservative interventions for managing urinary incontinence after prostate surgery found no studies on electrical or magnetic stimulation compared with no treatment, sham, or verbal/written instructions that reported on key outcomes. (10)

One RCT was identified on magnetic PFS for treating postprostatectomy urinary incontinence. Yokoyama et al. (2004) reported findings from a 3-arm randomized trial. (24) Thirty-six men (12 in each group) were randomized to extracorporeal magnetic PFS (NeoControl chair), functional electrical PFS, or pelvic floor exercises. The primary outcome was pad weight testing for up to 6 months after the 1-month treatment period. At 1 month after catheter removal, pad weight was significantly lower in the electrical PFS group than in the control group; at 2 months after catheter removal, pad weight was significantly lower in the magnetic PFS group compared with the control group; and, beginning at 3 months after catheter removal, there were no significant differences across arms in pad weight. Additionally, there were no significant differences between groups in quality of life measurements at any follow-up point. The trial lacked a sham magnetic stimulation group and therefore a placebo effect cannot be ruled out as an explanation for the short-term reduction in pad weight in the magnetic PFS treatment group.

Section Summary: Magnetic PFS for Urinary Incontinence

A systematic review of RCTs evaluating the use of magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the small number of trials with short-term follow-up, methodologic limitations, and heterogeneity in terms of patient populations, interventions, and outcome reporting.

One RCT evaluated magnetic PFS for the treatment of men with postprostatectomy urinary incontinence. There was a greater improvement in pad weight at 2 months in the magnetic PFS group than in the pelvic floor muscle exercises group but there were no significant differences between groups beginning at 3 months. Other outcomes also did not favor the magnetic PFS group. A 2023 systematic review was unable to identify studies on magnetic PFS evaluating outcomes of interest.

Magnetic PFS for Fecal Incontinence

Clinical Context and Therapy Purpose

The purpose of PFS in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with fecal incontinence. Risk factors for fecal incontinence are similar in men and women: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes. For women, current and past use of hormone therapy is an added risk factor. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence.

Interventions

The therapy being considered is magnetic PFS for fecal incontinence. The mechanism of action of a magnetic PFS procedure is similar to the electrical procedure, though using magnetic pulses to activate the pelvic floor musculature. The magnetic pulses are delivered without a probe, with patients sitting fully clothed in a specialized chair with an embedded magnet.

Comparators

The following therapies are currently being used to make decisions about fecal incontinence: nonsurgical treatment options and behavioral therapies. Nonsurgical treatment options for incontinence may include pharmacologic therapy, bowel training exercises, and electrical stimulation. Behavioral therapies include pelvic floor muscle training and diet.

Outcomes

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Treatment is for approximately 8 weeks, and follow-up is generally up to 6 months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

No studies were identified that evaluated magnetic PFS as a treatment of fecal incontinence.

Section Summary: Magnetic PFS for Fecal Incontinence
Current evidence is insufficient to draw conclusions about the efficacy of magnetic PFS to treat fecal incontinence.

Summary of Evidence
For individuals who have urinary incontinence who receive electrical pelvic floor stimulation (PFS), the evidence includes randomized controlled trials (RCTs) and systematic reviews. 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

For individuals who have urinary incontinence who receive magnetic PFS, the evidence includes RCTs and 2 systematic reviews. 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 that the technology results in an improvement in the net health outcome.

For individuals who have fecal incontinence who receive magnetic PFS, no relevant evidence was identified. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Gastroenterology

In 2021, the American College of Gastroenterology issued guidelines on the management of benign anorectal disorders. (25) In the section on fecal incontinence, pelvic floor stimulation (PFS) is not mentioned as a treatment option.

American Society of Colon and Rectal Surgeons

In 2023, the American Society of Colon and Rectal Surgeons updated an evidence-based guideline using GRADE methodology on treatment of fecal incontinence. (26) Dietary interventions and medical management are considered first-line treatments; PFS was not included in the recommendations.

American Urological Association et al.

In 2024, the American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) updated guidelines on the diagnosis and management of overactive bladder. (27) Electromagnetic therapy is included as an example of non-invasive therapy. The recommendation states, "Clinicians may offer select non-invasive therapies to all patients with OAB." However, the guidelines also state, "While safety profiles are excellent across modalities, with few adverse effects and a high risk-benefit ratio, all non-invasive therapies do not have equivalent efficacy, and the evidence base is highly variable. Most non-invasive therapies require long-term patient compliance to maintain a durable effect, and patients should be counselled as such before embarking on a course of a potentially lifelong therapy." There is no additional information specific to PFS in the guidelines.

Joint guidelines issued in 2019 by the AUA and the SUFU on management of post-prostatectomy urinary incontinence do not specifically address electrical or magnetic PFS as treatment options. Pelvic floor muscle training/exercise is recommended as first-line treatment for post-prostatectomy incontinence. (28)

National Institute for Health and Care Excellence (NICE)

In 2019, the NICE issued guidance on the management of urinary incontinence in women. (29) 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. (30) 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05952258	Magnetic Stimulation as a Treatment for Stress Urinary Incontinence	158	Jul 2026
Unpublished			
NCT04644614	Effectiveness of Magnetic Stimulation in Patients With Urinary Incontinence After Radical Prostatectomy: a Prospective Randomized Sham Controlled Clinical Study	40	Apr 2023 (unknown status)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	53899, 97014, 97032
HCPCS Codes	E0740, G0283

References

1. Gorina Y, Schappert S, Bercovitz A, et al. Prevalence of incontinence among older Americans. Vital Health Stat 3. Jun 2014; (36):1-33. PMID 24964267
2. Markland AD, Goode PS, Redden DT, et al. Prevalence of urinary incontinence in men: results from the national health and nutrition examination survey. J Urol. Sep 2010; 184(3):1022-1027. PMID 20643440

3. Abdelbary AM, El-Dessoukey AA, Massoud AM, et al. Combined vaginal pelvic floor electrical stimulation (pfs) and local vaginal estrogen for treatment of overactive bladder (OAB) in perimenopausal females. Randomized controlled trial (RCT). Urology. Sep 2015; 86(3):482-486. PMID 26135813
4. Leonardo K, Seno DH, Mirza H, et al. Biofeedback-assisted pelvic floor muscle training and pelvic electrical stimulation in women with overactive bladder: A systematic review and meta-analysis of randomized controlled trials. Neurourol Urodyn. Aug 2022; 41(6):1258-1269. PMID 35686543
5. Stewart F, Berghmans B, Bo K, et al. Electrical stimulation with non-implanted devices for stress urinary incontinence in women. Cochrane Database Syst Rev. Dec 22 2017; 12:CD012390. PMID 29271482
6. Shamliyan T, Wyman J, Kane R. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness (Comparative Effectiveness Review 36). Rockville, MD: Agency for Healthcare Research and Quality; 2012.
7. Moroni RM, Magnani PS, Haddad JM, et al. Conservative treatment of stress urinary incontinence: a systematic review with meta-analysis of randomized controlled trials. Rev Bras Ginecol Obstet. Feb 2016; 38(2):97-111. PMID 26883864
8. Sciarra A, Viscuso P, Arditi A, et al. A biofeedback-guided programme or pelvic floor muscle electric stimulation can improve early recovery of urinary continence after radical prostatectomy: A meta-analysis and systematic review. Int J Clin Pract. Oct 2021; 75(10):e14208. PMID 33811418
9. Berghmans B, Hendriks E, Bernards A, et al. Electrical stimulation with non-implanted electrodes for urinary incontinence in men. Cochrane Database Syst Rev. 2013; 6:CD001202. PMID 23740763
10. Johnson EE, Mamoulakis C, Stoniute A, et al. Conservative interventions for managing urinary incontinence after prostate surgery. Cochrane Database Syst Rev. Apr 18 2023; 4(4):CD014799. PMID 37070660
11. Zhu YP, Yao XD, Zhang SL, et al. Pelvic floor electrical stimulation for postprostatectomy urinary incontinence: a meta-analysis. Urology. Mar 2012; 79(3):552-555. PMID 22386394
12. Goode PS, Burgio KL, Johnson TM, 2nd, et al. Behavioral therapy with or without biofeedback and pelvic floor electrical stimulation for persistent postprostatectomy incontinence: a randomized controlled trial. JAMA. Jan 12 2011; 305(2):151-159. PMID 21224456
13. Yamanishi T, Mizuno T, Watanabe M, et al. Randomized, placebo controlled study of electrical stimulation with pelvic floor muscle training for severe urinary incontinence after radical prostatectomy. J Urol. Nov 2010; 184(5):2007-2012. PMID 20850831
14. Cohen-Zubary N, Gingold-Belfer R, Lambort I, et al. Home electrical stimulation for women with fecal incontinence: a preliminary randomized controlled trial. Int J Colorectal Dis. Apr 2015; 30(4):521-528. PMID 25619464
15. Norton C, Gibbs A, Kamm MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. Dis Colon Rectum. Feb 2006; 49(2):190-196. PMID 16362803
16. Vonthein R, Heimerl T, Schwandner T, et al. Electrical stimulation and biofeedback for the treatment of fecal incontinence: a systematic review. Int J Colorectal Dis. Nov 2013; 28(11):1567-1577. PMID 23900652

17. Schwandner T, Konig IR, Heimerl T, et al. Triple target treatment (3T) is more effective than biofeedback alone for anal incontinence: the 3T-AI study. Dis Colon Rectum. Jul 2010; 53(7):1007-1016. PMID 20551752
18. Schwandner T, Hemmelmann C, Heimerl T, et al. Triple-target treatment versus low-frequency electrostimulation for anal incontinence: a randomized, controlled trial. Dtsch Arztebl Int. Sep 2011; 108(39):653-660. PMID 22013492
19. Hosker G, Cody JD, Norton CC. Electrical stimulation for faecal incontinence in adults. Cochrane Database Syst Rev. 2007; 3:CD001310. PMID 17636665
20. Lim R, Lee SW, Tan PY, et al. Efficacy of electromagnetic therapy for urinary incontinence: A systematic review. Neurourol Urodyn. Nov 2015; 34(8):713-722. PMID 25251335
21. Yamanishi T, Homma Y, Nishizawa O, et al. Multicenter, randomized, sham-controlled study on the efficacy of magnetic stimulation for women with urgency urinary incontinence. Int J Urol. Apr 2014; 21(4):395-400. PMID 24118165
22. Gilling PJ, Wilson LC, Westenberg AM, et al. A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs sham therapy in the treatment of women with stress urinary incontinence. BJU Int. May 2009; 103(10):1386-1390. PMID 19154474
23. Lim R, Liong ML, Leong WS, et al. Pulsed Magnetic Stimulation for Stress Urinary Incontinence: 1-Year Followup Results. J Urol. May 2017; 197(5):1302-1308. PMID 27871927
24. Yokoyama T, Nishiguchi J, Watanabe T, et al. Comparative study of effects of extracorporeal magnetic innervation versus electrical stimulation for urinary incontinence after radical prostatectomy. Urology. Feb 2004; 63(2):264-267. PMID 14972468
25. Wald A, Bharucha AE, Limketkai B, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. Am J Gastroenterol. Oct 01 2021; 116(10):1987-2008. PMID 34618700
26. Bordeianou LG, Thorsen AJ, Keller DS, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Fecal Incontinence. Dis Colon Rectum. May 01 2023; 66(5):647-661. PMID 36799739
27. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. J Urol. Jul 2024; 212(1):11-20. PMID 38651651
28. Sandhu JS, Breyer B, Comiter C, et al. Incontinence after Prostate Treatment: AUA/SUFU Guideline. J Urol. Aug 2019; 202(2):369-378. PMID 31059663
29. National Institute for Health and Clinical Excellence (NICE) Guideline. Urinary Incontinence and Pelvic Organ Prolapse in Women: Management. 2019. Available at: <https://www.nice.org> (accessed June 11, 2024).
30. National Institute for Health and Clinical Excellence (NICE). Faecal incontinence in adults: management [CG49]. 2007. Available at: <https://www.nice.org> (accessed June 10, 2024).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Document updated with literature review. Coverage unchanged. Added references 10, 23, and 27.
11/15/2023	Document updated with literature review. Coverage unchanged. Added references 4, 23, and 24; others removed.
10/15/2022	Reviewed. No changes.
11/01/2021	Document updated with literature review. Coverage unchanged. The following references were added/updated: 4, 6, 9, 24, 25 and 29.
10/15/2020	Reviewed. No changes.
11/15/2019	Document updated with literature review. Coverage unchanged. The following references were added/updated: 3, 25, and 28.
10/01/2018	Reviewed. No changes.
11/15/2017	Document updated with literature review. Coverage unchanged.
11/01/2016	Reviewed. No changes.
05/01/2015	Document updated with literature review. The following was added to Coverage: Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation, or PFS) as a treatment of fecal incontinence is considered experimental, investigational and/or unproven. In addition, the title was changed from "Pelvic Floor Stimulation (PFS) as a Treatment of Urinary Incontinence".
10/15/2013	Document updated with literature review. Coverage unchanged. Description and Rationale completely revised.
06/01/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
09/01/2007	Revised/updated entire document
11/15/2005	Revised/updated entire document
04/01/2003	CPT/HCPCS code(s) updated
11/01/2000	CPT/HCPCS code(s) updated
03/01/2000	Revised/updated entire document
11/01/1998	Revised/updated entire document
12/01/1990	New medical document