



Kansas City

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Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

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Next Review: 2/2020

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence. This is considered investigational.

Please note that this is a type of electrical stimulation that is considered a benefit exclusion in many health plan contracts.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

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**.

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: • With urinary incontinence	Interventions of interest are: • Electrical pelvic floor stimulation	Comparators of interest are: • Behavioral therapy (eg, 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 (eg, fluid intake, pelvic floor muscle	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related

		training) • Medication	morbidity
Individuals: • With urinary incontinence	Interventions of interest are: • Magnetic pelvic floor stimulation	Comparators of interest are: • Behavioral therapy (eg, 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 (eg, diet, pelvic floor muscle training) • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity

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.

For individuals who have urinary incontinence who receive electrical 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 multiple 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. Moreover, meta-analyses of RCTs have also not found a significant benefit of significant 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. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Several RCTs have evaluated electrical PFS to treat 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 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 small number of trials with short-term follow-up, methodologic limitations, and heterogeneity in terms of patient populations, interventions, and outcomes reporting. There was

only 1 RCT evaluating magnetic stimulation for treating men with postprostatectomy urinary 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.

Background Incontinence

Incontinence, especially urinary, 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 and 17% issues with fecal incontinence.¹

Treatment

Nonsurgical treatment options for incontinence may include pharmacologic therapy, pelvic floor muscle exercises, bowel or bladder training exercises, electrical stimulation, and neuromodulation.

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 (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.

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 FDA through the 510(k) process. Predicate devices also used to treat urinary incontinence, include 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) was approved by FDA through the premarket approval 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 FDA. The device is intended to treat male and female urinary and fecal incontinence.

Rationale

This evidence review was created in April 1998 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through June 4, 2018.

The urinary incontinence portion of the review was informed by 2 TEC Assessments (2000), one on electrical pelvic floor stimulation (PFS) and the other on magnetic PFS.^{2,3}

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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.

Pelvic Floor Stimulation

Clinical Context and Test Purpose

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

The question addressed in this evidence review is: Does the use of PFS (electrical or magnetic) improve net health outcomes in patients with urinary or fecal incontinence?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant populations of interest are patients with urinary or fecal 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.

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.

Interventions

The therapy being considered is for urinary and fecal incontinence in electric and magnetic PFS. 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.

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 and fecal incontinence: electrical PFS and magnetic PFS, both of which are behavioral therapies (eg, monitoring fluid intake, pelvic floor muscle training, diet), and medications.

Outcomes

The general outcomes of interest include reduction in symptoms (eg, number of incontinence episodes) and improvements in quality of life and cure rates.

Timing

Short-term results can be measured at 6 months. Longer term follow-up may be necessary to determine if treatment has durable effects.

Setting

Electrical PFS is administered in a physician's office or a physical therapy facility. Patients may also be trained on the use of a rental PFS system to continue treatments at home. Magnetic PFS is administered in a physician's office.

Electrical PFS FOR Urinary Incontinence

Women

Systematic Reviews

A TEC Assessment (2000) concluded there was insufficient evidence that electrical PFS improved health outcomes compared with placebo or other behavioral therapies in women with stress, urge, or mixed incontinence.²

Subsequently, several systematic reviews of the literature with pooled study findings have been published.

In a systematic review and cost-effectiveness analysis published by the U.K. Health Technology Assessment program, Imamura et al (2010) identified 8 RCTs comparing electrical stimulation with no active treatment; a sham control was used in 6 studies.⁴ A pooled analysis of findings (all comparison groups combined) did not find a statistically significant difference between groups in cure rate (6% in each group; odds ratio, 1.10; 95% confidence interval [CI], 0.41 to 2.94). A pooled analysis of cure rates from the 5 studies comparing electrical PFS with pelvic floor muscle training did not show a significant difference between groups; the cure rates were 24% and 11%, respectively (odds ratio, 2.65; 95% CI, 0.82 to 8.60). When the comparison was limited to studies evaluating electrical stimulation and no active treatment, there was a higher rate of improvement with electrical stimulation (37% vs 14%; odds ratio, 3.93; 95% CI, 1.43 to 10.8). In studies without a sham intervention group, a placebo effect of electrical stimulation could not be ruled out. Reviewers concluded that there is insufficient

evidence to recommend electrical stimulation on a routine basis for treatment of stress urinary incontinence.

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.⁵ 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 a relative risk (RR) of 2.86 (95% CI, 1.57 to 5.23). A pooled analysis of 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.⁶ Five trials (total N=221 women) were identified comparing intravaginal electrical PFS with a control. There were insufficient data on cure rates (eg, 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 vs 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.

Randomized Controlled Trials

Findings of representative RCTs on electrical stimulation for urinary incontinence in women are described next. Goode et al (2003) reported on a trial that randomized 200 women with primarily stress incontinence to 8 weeks of behavioral training, 8 weeks of behavioral training plus home PFS, or self-administered behavioral training alone using a self-help booklet.⁷ The main outcomes measures were patient-reported bladder diaries and changes in quality of life. Patients in all 3 groups reported significant reductions in incontinence; there were no significant differences between groups.

Castro et al (2008) published a single-blind RCT comparing treatment with pelvic floor muscle training, electrical PFS, vaginal cones, or a no-treatment control group in women with confirmed urodynamic stress urinary incontinence who did not have urge incontinence.⁸ Outcome assessment was blinded, but patients were not blinded to treatment group. A total of 118 women were randomized; 17 (14%) women withdrew from the trial. A total of 101 women completed the study and were included in the analysis (26 in the pelvic floor muscle training group, 27 in the electrical stimulation group, 24 in the vaginal cones group, 24 in the untreated group). The primary outcome was the proportion of women with a negative pad test (ie, weight <2 g). At 6 months, outcomes were similar in the 3 treatment

groups, but significantly fewer women in the no-treatment group had a negative pad test. The numbers of women with negative pad tests were 12 (46%) in the pelvic floor muscle training group, 13 (48%) in the electrical stimulation group, 11 (45%) in the vaginal cone group, and 2 (8.0%) in the untreated control group.

Abdelbary et al (2015) published a 3-group RCT evaluating women with overactive bladder and treated with electrical PFS, local vaginal estrogen treatment, or a combination of both interventions.⁹ The trial included 315 women (105 women per group). Electrical PFS was administered using a vaginal probe. At 6-month follow-up, there were statistically significant differences among the 3 groups in outcomes that included the number of voids per day, the number of incontinence episodes, the number of urgency episodes, and the quality of life score ($p < 0.001$ for each outcome). In a post hoc analysis, there was more improvement in the electrical PFS group than in the estrogen-only group for all key variables. The combined treatment group had better results than the estrogen-only group on several outcomes, but not voiding frequency per day, the number of incontinence episodes, or quality of life.

Men With Postprostatectomy Urinary Incontinence

Systematic Reviews

Several systematic reviews of RCTs have been published. A Cochrane review by Berghmans et al (2013) identified 6 RCTs on electrical PFS with nonimplanted electrodes for postprostatectomy urinary incontinence in men.¹⁰ 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.

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 (total 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

(pelvic floor muscle training 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 ($p=0.001$), 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 men performed pelvic floor muscle training. 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 g 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 ($p>0.05$). Change in the amount of daily leakage from baseline differed significantly between groups at 1 month (-528 g in the active

treatment group vs -257 g in the sham group, $p < 0.01$), but not at the other follow-up time points.

Section Summary: Electrical PFS for Urinary Incontinence

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.

There are a few small RCTs evaluating electrical PFS as a treatment of postprostatectomy urinary incontinence in men. These studies have reported improvements on 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. Three pooled analyses of RCTs were identified: one did not find a statistically significant benefit of electrical PFS when added to pelvic floor muscle exercises; a second found a short-term benefit of electrical PFS compared with no stimulation or sham; and the third did not find a short- or long-term benefit of electrical PFS compared with any control condition.

Electrical PFS for Fecal Incontinence

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.¹⁴ They identified 13 RCTs that used one or both of these treatments and reported health outcomes (eg, 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 review included only 2 RCTs on electrical PFS^{15,16} 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.¹⁷ 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

Representative RCTs published are described next. 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).¹⁸ 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 end points were an improvement 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) 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.¹⁹ 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 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=0.92). In a completer analysis, the median change in symptoms was 2 in the active treatment group and 1 in the sham group (p=0.74). 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 one 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

Women

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 (total N=484 patients). Treatment protocols (eg, 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 Food and Drug Administration 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 end point was change in number of urinary incontinence episodes per week, as reported in a patient diary. The decrease in the weekly number (standard deviation) of incontinence episodes was 13 (11) in the active treatment group compared with 9 (13) in the sham group (p=0.038). Patients in the active stimulation group had significantly better results on some secondary outcomes (eg, number of urgency episodes per 24 hours), but not others (eg, 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.

Men With Postprostatectomy Urinary Incontinence

One RCT was identified on magnetic PFS for treating postprostatectomy urinary incontinence. Yokoyama et al (2004) reported findings from a 3-arm randomized trial.²³ 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 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.

MAGNETIC PFS FOR Fecal Incontinence

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

Section Summary: Magnetic PFS for Fecal Incontinence

Current evidence is insufficiently robust 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 PFS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, 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. 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 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.

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.

Supplemental Information

Practice Guidelines and Position Statements

American Urological Association

The American Urological Association (2014) published guidelines on the diagnosis and management of overactive bladder.²⁴ Neither electrical pelvic floor stimulation (PFS) nor magnetic PFS was mentioned as recommended first-, second-, or third-line treatment options.

European Association of Urology

The latest version of the European Association of Urology clinical guidelines on the assessment and nonsurgical management of urinary incontinence was published in 2018.²⁵ The following statements were made on electrical PFS and magnetic PFS:

“Do not offer electrical stimulation with surface electrodes (skin, vaginal, anal) alone for the treatment of stress urinary incontinence.” (strong recommendation)

“Do not offer magnetic stimulation for the treatment of urinary incontinence or overactive bladder in women.” (strong recommendation)

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE; 2015) issued guidance on the management of urinary incontinence in women.²⁶ 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. 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.

NICE (2007) issued guidance on the management of fecal incontinence in adults.²⁷ (This guidance was last reviewed by NICE in 2014.) The document stated that the evidence on electrical stimulation for treatment of fecal incontinence was inconclusive. 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.

American College of Physicians

The American College of Physicians (2014) issued guidelines on the nonsurgical management of urinary incontinence.²⁸ Electrical PFS and magnetic PFS were not discussed.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The national coverage determination for Non-Implantable Pelvic Floor Electrical Stimulator (230.8) stated: “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.”²⁹ The effective date was June 19, 2006. The document did not mention fecal incontinence.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT02599831	Efficacy of Electrical Pudendal Nerve Stimulation for Patients with Postprostatectomy Incontinence	96	Feb 2017 (completed)
NCT01924728 ^a	A Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Investigate the Effects of Transpelvic Magnetic Stimulation (Using QRS®-1010 PelviCenter) in Patients with Stress Urinary Incontinence	120	Feb 2016 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Billing Coding/Physician Documentation Information

53899	Unlisted procedure, urinary system
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
E0740	Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

ICD-10 Codes:

F98.0	Enuresis not due to a substance or known physiological condition
F98.1	Encopresis not due to a substance or known physiological condition
N39.3	Stress incontinence (female) (male)
N39.41-	Other specified urinary incontinence
N39.498	
R15.9	Full incontinence of feces

Additional Policy Key Words

Incontinence, Pelvic Floor Stimulation

Pelvic Floor Stimulation

Policy Implementation/Update Information

2/1/07	New policy, considered investigational
8/1/07	No policy statement changes.
2/1/08	No policy statement changes.
2/1/09	No policy statement changes. Coding updated; code 0029T is a terminated code.
2/1/10	No policy statement changes.
2/1/11	No policy statement changes.
2/1/12	No policy statement changes.
2/1/13	No policy statement changes.
2/1/14	No policy statement changes.
2/1/15	“And fecal” added to policy title. Statement added that electrical or magnetic stimulation of the pelvic floor muscles as a treatment for fecal incontinence is considered investigational.
2/1/16	No policy statement changes.
4/1/16	No policy statement changes.
2/1/17	No policy statement changes.
2/1/18	No policy statement changes.
2/1/19	No policy statement changes.

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