Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

Policy Number: 1.01.17  Last Review: 2/2017
Origination: 2/2007  Next Review: 2/2018

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

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<td>Interventions of interest are: • Electrical pelvic floor stimulation</td>
<td>Comparators of interest are: • Behavioral therapy (eg, fluid intake, pelvic floor muscle training) • Medication</td>
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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**

Pelvic floor stimulation (PFS) involves the electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation or, more recently, extracorporeal electromagnetic (also called magnetic) pulses. The intent of the intervention is to stimulate the pudendal nerve in order to activate the pelvic floor musculature; it is thought that activation of these muscles will lead to improved urethral closure. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. The methods of electrical PFS have varied in location (e.g., vaginal, rectal), stimulus frequency, stimulus intensity or amplitude, pulse duration, pulse to rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, and overall time period for device use between clinical and home settings. Variation in the amplitude and frequency of the electrical pulse is used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the type of etiology of incontinence, i.e., either detrusor instability, stress incontinence, or a mixed pattern. Magnetic PFS does not require an internal electrode; instead, patients sit fully clothed on a specialized chair with an embedded magnet.

Patients receiving electrical PFS may undergo treatment in a physician’s office or physical therapy facility, or patients may undergo initial training in a physician’s office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS may be delivered in the physician’s office.

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

**Regulatory Status**

Several electrical stimulators have been cleared by the U.S. Food and Drug Administration (FDA). In March 2006, the MyoTrac Infiniti™ (Thought Technology, Ltd.), a nonimplanted electrical stimulator for treating urinary incontinence, was cleared for marketing by the 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 Inc.). In 2011, the itouch Sure
Pelvic Floor Exerciser (Tenscare, U.K.) was cleared for marketing. This product is being marketed in the U.S. as EmbaGYN® by Everett Laboratories (Chatham, NJ).

In June 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus, Inc) was approved by the 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 February 2014, the InTone®MV (InControl Medicine; Brookfield, WI), a nonimplantable device that provides electrical stimulation and/or biofeedback via manometry, was cleared by FDA. The device is intended for the treatment of male and female urinary and fecal incontinence.

**Rationale**

This evidence review was created in April 1998 and updated regularly with searches of the MEDLINE database. The urinary incontinence portion of the review was based on 2 TEC Assessments, both completed in 2000, one on electrical pelvic floor stimulation (PFS) and the other on magnetic PFS.¹ ² Most recently, the literature was reviewed through August 24, 2016.

**Electrical PFS FOR Urinary Incontinence**

**Women**

**Systematic Reviews**

A 2000 TEC Assessment concluded that 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.¹

Subsequently, several systematic reviews of the literature that pool study findings have been published. Systematic reviews of randomized controlled trials (RCTs) from the U.K. Health Technology Assessment (HTA) program and the U.S. Agency for Healthcare Research and Quality (AHRQ) were released in 2010 and 2012. Both reviews addressed a variety of nonsurgical treatments for women with urinary incontinence; the HTA report was limited to studies on stress incontinence.

In a systematic review and cost-effectiveness analysis published for the HTA program, HTA reviewers identified 8 RCTs comparing electrical stimulation with no active treatment; a sham control was used in 6 of the studies.³ A pooled analysis of findings (all comparison groups combined) did not find a statistically significant difference between groups in cure rate, which was 6% in each group (odds ratio [OR], 1.10; 95% confidence interval [CI], 0.41 to 2.94). Moreover a pooled analysis of cure rates from the 5 studies comparing electrical stimulation with pelvic floor muscle training did not show a significant difference between groups; the cure rates were 24% and 11%, respectively (OR=2.65; 95% CI, 0.82 to 8.60).
When the comparison was limited to studies comparing electrical stimulation with no active treatment, there was a higher rate of improvement with electrical stimulation (37% vs 14%; OR=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. The reviewers concluded that there is insufficient evidence to recommend electrical stimulation on a routine basis for treatment of stress urinary incontinence.

The AHRQ-funded comparative effectiveness review identified 9 RCTs evaluating electrical intravaginal stimulation in women with urgency, stress, or mixed incontinence. Eight of the 9 studies were published in 2000 or earlier; nearly all used a sham treatment as the control condition. A pooled analysis of continence rates in 8 RCTs comparing electrical stimulation with no active treatment yielded a relative risk (RR) of 2.86 (95% CI, 1.57 to 5.23). A pooled analysis of improvement in incontinence symptoms yielded a relative risk of 2.01 (95% CI, 1.28 to 3.15). The AHRQ report concluded that a high level of evidence suggests electrical stimulation is associated with increased continence rates and improved urinary incontinence.

In 2016, Moroni et al published a systematic review of conservative treatment of stress urinary incontinence. Five trials (total N=221 women) were identified comparing intravaginal electrical stimulation versus 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 significantly greater reduction in pad weight in the treatment versus control groups (mean difference [MD], -9.15; 95% CI, -17.22 to -1.08). A pooled analysis of 2 studies found significantly greater improvement in incontinence-specific quality of life (QOL) in the electrical PFS group than in the control group (MD = -1.44; 95% CI, -1.94 to -0.95). Three studies were included in a pooled analysis of number of incontinence episodes; findings of this meta-analysis were not reported. The reviewers stated that, among all conservative treatments assessed, evidence was strongest in support of pelvic floor muscle stimulation, 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.

In 2003, Goode et al reported on the outcomes of a trial that randomized 200 women with primarily stress incontinence to undergo either 8 weeks of behavioral training, 8 weeks of behavioral training plus home PFS, or self-administered behavioral training alone using a self-help booklet. The main outcomes measurements were the results of bladder diaries and changes in QOL. Patients in all 3 groups reported significant improvements in incontinence; there were no significant differences between groups.

In 2008, Castro et al published a single-blind RCT comparing treatment with pelvic floor muscle training, electrical stimulation or vaginal cones, or a no-treatment
control group in women with proven urodynamic stress urinary incontinence who did not have urge incontinence.\textsuperscript{7} Outcome assessment was blinded, but patients were not blinded to treatment group. A total of 118 women were randomized; 17 (14\%) withdrew from the study. 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 grams). 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.

In 2015, Abdelbary et al published a 3-group RCT in women with overactive bladder comparing electrical PFS, local vaginal estrogen treatment, and a combination of both interventions.\textsuperscript{8} The trial included 315 women, 105 per group. Electrical stimulation 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 QOL score (p<0.001 for each outcome). In a post hoc analysis, improvement was better 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 QOL.

Men With Postprostatectomy Urinary Incontinence

Systematic Reviews
Several systematic reviews of RCTs have been published. A 2013 Cochrane review identified 6 RCTs on electrical stimulation with nonimplanted electrodes for postprostatectomy urinary incontinence in men.\textsuperscript{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 not a 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 stimulation alone were not pooled.

A 2012 meta-analysis by Zhu et al had similar findings.\textsuperscript{10} This review also evaluated electrical PFS used to treat postprostatectomy urinary incontinence. The 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 stimulation 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 stimulation on continence levels 6 to 12 months after prostatectomy (RR=1.03; 95\% CI, 0.88 to 1.20).
Randomized Controlled Trials
Representative trials on men with postprostatectomy urinary incontinence are described in the following section.

In 2011, Goode et al published the results of an RCT comparing behavioral therapy alone with behavioral therapy in combination with biofeedback and electrical PFS. 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 and bladder control exercises; n=70), behavioral therapy plus biofeedback and electrical stimulation (n=70), and a delayed-treatment control group (n=68). The biofeedback and 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, and were followed at 6 and 12 months. The primary efficacy outcome was 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 (ITT) analysis of the primary outcome, the mean reduction in incontinent episodes was 55% (28 to 13 episodes/wk) in the behavioral therapy group, 51% (from 26 to 12 episodes/wk) in the behavior-plus group, and 24% (from 25-20 episodes/wk) 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 on 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, 12/70 [17%] in the behavior-plus group) than in the control group (4/68 [6%]), but the group receiving biofeedback and electrical stimulation did not have a significantly higher continence rate than the group receiving behavioral therapy alone. The study did not isolate the effect of electrical PFS, and the combined behavior-plus intervention did not result in better outcomes than behavioral therapy alone.

In 2010, Yamanishi et al published findings of an RCT comparing electrical stimulation with a sham control group. This trial, conducted in Japan, was double-blind; in it, 56 men with severe postprostatectomy urinary incontinence were randomized to receive active (n=26) or sham (n=30) electrical stimulation. All men performed pelvic floor muscle training. Active or sham electrical stimulation was performed until incontinence was resolved or until the end of the study at 12 months. A total of 47 patients (22 in the active stimulation group, 25 in the sham group) completed the study. The continence rate, defined as loss of 8 grams or less of urine during a 24-hour pad test, was the primary efficacy outcome. There was a statistically significantly higher rate of continence at 1, 3, and 6 months in the active stimulation group compared with the sham group, but the difference between groups was not statistically significant at 12 months. Rates of continence in the active electrical stimulation 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%). Findings of the 24-hour pad tests were also reported in different ways. Differences in the amount (number of grams) of daily leakage did not differ significantly between groups at any follow-up time point. 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, -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**

Multiple RCTs on electrical PFS for treatment of women with urinary incontinence have been published, mainly before 2001. Meta-analyses of RCTs have had mixed 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 stimulation, but have tended to be limited by failure to isolate the effect of electrical simulation and/or lack of a sham comparator or comparison with an accepted treatment. Three pooled analyses of RCTs were identified; 1 did not find a statistically significant benefit of electrical stimulation when added to pelvic floor muscle exercises, a second found a short-term benefit of electrical stimulation compared with no stimulation or sham, and the third did not find a short- or long-term benefit of electrical stimulation compared with any control condition.

**Electrical PFS for Fecal Incontinence**

**Systematic Reviews**

In 2007, a Cochrane review identified 4 RCTs evaluating electrical stimulation as a treatment of fecal incontinence in adults. One trial was sham-controlled, 1 compared electrical stimulation with levatorplasty, and 2 used electrical stimulation as an adjunct treatment. The Cochrane investigators did not pool study findings; they concluded that there is insufficient evidence to draw conclusions on the efficacy of electrical stimulation for treating fecal incontinence.

More recently, a 2013 systematic review by Vonthein et al searched for studies on the impact of biofeedback and/or electrical stimulation for treating fecal incontinence in adults. They identified 13 RCTs that used 1 or both of these treatments and reported health outcomes (eg, remission or response rates using validated scales). A pooled analysis of study results did not find a statistically significant higher rate of remission when electrical stimulation was compared to a control intervention (RR=0.47; 95% CI, 0.13 to 1.72). A pooled analysis of studies comparing the combination of electrical stimulation and biofeedback with electrical stimulation 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 stimulation. Also, the
confidence interval was very wide, indicating an imprecise estimate of treatment effect. The Vonthein review included only 2 RCTs on electrical stimulation\textsuperscript{15,16} that were published after the Cochrane review just described. These 2 trials included the combination of amplitude-modulated medium-frequency stimulation and biofeedback. Electrical stimulation was not evaluated in the absence of biofeedback.

\textbf{Randomized Controlled Trials}

Representative RCTs published are described next.

In 2006, Norton et al in the U.K. published a sham-controlled randomized trials that included 90 adults with fecal incontinence.\textsuperscript{17} Patients used a home electric stimulation device for 8 weeks. Those allocated to active treatment had 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 hypothesized to have a 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 study. In an ITT 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; again, the difference between groups was not statistically significant (p=0.74). Moreover, groups did not differ significantly on other secondary outcomes such as the frequency of urge or passive incontinence after treatment.

A 2015 RCT from Israel randomized 42 women with fecal incontinence to 6 weeks of electrical stimulation (n=22) or biofeedback training (n=20).\textsuperscript{18} Biofeedback sessions were conducted in-clinic and electrical stimulation sessions at home following an initial training in-clinic. A total of 36 (86\%) women completed the study and were included in the analysis; the analysis was not ITT. The trial’s primary end points were improvement in frequency of fecal, urine, and gas incontinence, assessed by visual analog scale (VAS) scores. There were no statistically significant differences between groups for the primary outcomes. For example, the mean VAS score 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 VAS score was 1.1±2.1 and 0.3±0.5 at follow-up. The p value for the between-group differences in this outcome was not statistically significant. For within-group changes, the electrical stimulation group improved significantly on solid stool incontinence but not liquid stool or gas incontinence, and the biofeedback group did not improve significantly on any of the fecal incontinence outcomes.

\textbf{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**

**Women**

**Systematic Review**
A systematic review of RCTs on magnetic stimulation for treatment of urinary incontinence was published in 2015 by Lim et al. The reviewers identified 8 blinded sham-controlled trials (total N=484 patients). Treatment protocols (eg, frequency, duration of electrical stimulation) 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 improvement in the continence rate found significantly greater improvement in the treatment versus 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 also not pooled for other outcomes. The reviewers noted that the evidence was limited by low quality trials with short-term follow-up.

**Randomized Controlled Trials**
In 2014, Yamanishi et al in Japan published an industry-sponsored evaluation of magnetic stimulation provided to women with urinary urgency using an armchair-type stimulator. The device was produced by a Japanese company and does not appear to be FDA approved. Patients received either 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 the 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; the difference between groups was statistically significant (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 2009 sham-controlled RCT evaluating magnetic stimulation using the NeoControl chair did not find evidence that stimulation improved outcomes. In this trial, published by Gilling et al in New Zealand, sham treatment involved inserting a thin aluminum plate in the chair to prevent penetration of the magnetic field. 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 QOL 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 outcome analysis.

**Men With Postprostatectomy Urinary Incontinence**

One RCT was identified on magnetic stimulation for treating postprostatectomy urinary incontinence. The Japanese study was published in 2004 by Yokoyama et al and reported findings from a 3-arm randomized trial. Thirty-six men (12 in each group) were randomized to receive extracorporeal magnetic stimulation (NeoControl chair), functional electrical stimulation, 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 stimulation group than in the control group; at 2 months, pad weight was significantly lower in the magnetic stimulation group compared with the control group; and, beginning at 3 months, there were no significant differences in pad weight. There were also no significant differences between groups in QOL measures at any follow-up point. The trial lacked a sham magnetic stimulation group; a placebo effect might at least partially explain the short-term reduction in pad weight in the magnetic stimulation treatment group.

**Section Summary: Magnetic PFS for Urinary Incontinence**

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 outcome reporting. One RCT evaluated magnetic stimulation for treatment of men with postprostatectomy urinary incontinence. There was greater improvement in pad weight at 2 months in the magnetic stimulation group than in the pelvic floor muscle exercises group, but there were no significant differences between groups beginning at 3 months and other outcomes did not favor the magnetic stimulation 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**

No RCTs or non-RCTs were identified.

**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 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.

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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**
In 2014, the American Urological Association published guidelines on diagnosis and management of overactive bladder. Electrical PFS and magnetic PFS were not mentioned as recommended first-, second-, or third-line treatment options.

**European Association of Urology**
In 2012, the European Association of Urology published clinical guidelines on the management of urinary incontinence. The guidelines did not recommend treatment or urinary incontinence with electrical stimulation using surface electrodes alone, and did not recommend treatment with magnetic stimulation.
National Institute for Health and Clinical Excellence
In 2015, the National Institute for Health and Clinical Excellence (NICE) issued guidance on the management of urinary incontinence in women.\textsuperscript{25} NICE stated that electrical stimulation, alone or as an adjunct to pelvic floor muscle training, should not be routinely used in the treatment of women with overactive bladder. The guidance 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.”

In 2007, NICE issued guidance on management of fecal incontinence in adults.\textsuperscript{26} (The guideline decision was last reviewed by NICE in 2014.) The document stated that 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 should be considered for specialized management.

American College of Physicians
In 2014, the American College of Physicians issued guidelines on the nonsurgical management of urinary incontinence.\textsuperscript{27} Electrical PFS was not discussed.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
National coverage determination for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)\textsuperscript{28} 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.” The document did not mention fecal incontinence.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in September 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

References


**Billing Coding/Physician Documentation Information**

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<th>Description</th>
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<tr>
<td>53899</td>
<td>Unlisted procedure, urinary system</td>
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<tr>
<td>97014</td>
<td>Application of a modality to one or more areas; electrical stimulation (unattended)</td>
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<tr>
<td>97032</td>
<td>Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes</td>
</tr>
<tr>
<td>E0740</td>
<td>Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer</td>
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**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-N39.498** Other specified urinary incontinence
- **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.

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