Policy Statement

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) is considered investigational as a treatment for either of the following:

- Urinary incontinence
- Fecal incontinence

Policy Guidelines

Pelvic Floor Stimulation Devices
Examples of U.S. FDA approved pelvic floor muscle stimulation devices for urinary incontinence include, but are not limited to:

- BION® device - Pudendal nerve stimulation
- EmbaGYN®
- InTone™ MV
- Minnova™ Pelvic Floor Stimulation System
- MyoTrac Infiniti™
- NeoControl® Pelvic Floor Therapy System
- Pathway™ CTS 2000

Coding
The following CPT/HCPCS codes may be billed for pelvic floor stimulation; however they are not specific to this procedure:

- 53899: Unlisted procedure, urinary system
- 97014: Application of a modality to 1 or more areas; electrical stimulation (unattended)
- 97032: Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
- G0283: Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

The following HCPCS code is specific to the pelvic floor stimulator device:

- E0740: Non-implanted pelvic floor electrical stimulator, complete system

Description

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

Related Policies

- Percutaneous Tibial Nerve Stimulation
- Sacral Nerve Neuromodulation/Stimulation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the
time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of the FDA-approved technologies on the basis of medical necessity alone.

### 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; Montreal West, Québec), 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; Raleigh, NC) and the InCare® PRS (Hollister; Libertyville, IL). In 2011, the iTouch Sure Pelvic Floor Exerciser (TensCare, Epson, UK) was cleared for marketing. This product is being marketed in the United States as EmbaGYN® (Everett Laboratories, Chatham, NJ).

In June 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus; Marietta, GA) 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 Medical, Brookfield, WI), 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

#### Background

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. The intent of the intervention is to stimulate the pudendal nerve to activate the pelvic floor musculature; it is thought that activation of these muscles will 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 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 administered in the physician’s office.
PFS was first proposed as a treatment for urinary incontinence and later 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.

**Literature Review**

The urinary incontinence portion of the review was based on 2 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessments, both completed in 2000, one on electrical pelvic floor stimulation (PFS) and the other on magnetic PFS.1,2

**Electrical PFS for Urinary Incontinence**

**Women**

**Systematic Reviews**

A 2000 TEC Assessment 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.1

Subsequently, several systematic reviews of the literature, whose authors pooled 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 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. 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.4 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 cure 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 an RR of 2.01 (95% CI, 1.28 to 3.15). The AHRQ report concluded that a high level of evidence suggested electrical stimulation is associated with increased cure rates, and that such stimulation improved urinary incontinence.

In 2016, Moroni et al published a systematic review of conservative treatment of stress urinary incontinence.5 Five trials (total N=221 women) were identified comparing intravaginal electrical stimulation with a 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 vs control groups (mean difference [MD], -9.15; 95% CI, -17.22 to -1.08). A pooled analysis of 2 studies found a significantly greater improvement in incontinence-specific quality of life (in the electrical PFS group than in the control group (MD =-
1.01.17 Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

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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. 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. For example, in 2003, Goode et al reported on the outcomes of 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. The main outcomes measurements were the results of bladder diaries and changes in quality of life. 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, vaginal cones, or a no-treatment control group in women with proven urodynamic stress urinary incontinence who did not have urge incontinence. 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 (i.e., 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.

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. The trial included 315 women (105 women 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 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 Post Prostatectomy 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 post prostatectomy urinary incontinence in men. 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 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.

A 2012 meta-analysis by Zhu et al had similar findings. Reviewers also evaluated electrical PFS used to treat post prostatectomy urinary incontinence. They 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 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 of men with post prostatectomy urinary incontinence are now described. For example, in 2011, Goode et al published the results of an RCT comparing behavioral therapy alone with behavioral therapy plus biofeedback and electrical PFS.\(^1\) The trial included 208 men with urinary incontinence persisting at least 1 year after radical prostatectomy. Men with pre-prostatectomy 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; they were then given follow-up 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 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, 12/70 [17%] in the behavior-plus group) than in the control group (4/68 [6%]); however, the group receiving biofeedback and electrical stimulation 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.

In 2010, Yamanishi et al published findings of an RCT comparing electrical stimulation with a sham control group.\(^2\) This trial, conducted in Japan, was double-blinded; in it, 56 men with severe post prostatectomy urinary incontinence were randomized to 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. 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 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 than in the sham group, but the difference between groups was not statistically significant at 12 months. The numbers of men reported as continent 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%), respectively. 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 points. 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**

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 post prostatectomy urinary incontinence in men. These studies have reported improvements on some outcomes with electrical stimulation but also have limitations, such as: failure to isolate the effect of electrical simulation; 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 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. They identified one trial that used multiple treatments and two that used electrical stimulation alone. Reviewers 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 one 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 a statistically significant higher rate of remission when comparing electrical stimulation with a control intervention (RR=0.47; 95% CI, 0.13 to 1.72). A pooled analysis of studies comparing electrical stimulation plus 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. Additionally, the confidence interval was very wide, indicating an imprecise estimate of treatment effect. The Vonthein review included only 2 RCTs on electrical stimulation 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.

**Randomized Controlled Trials**

Representative RCTs published are described next. For example, in 2006, Norton et al in the U.K. published a sham-controlled randomized trials that included 90 adults with fecal incontinence. Patients used a home electric stimulation 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; 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 allocated 42 women with fecal incontinence to 6 weeks of electrical stimulation (n=22) or biofeedback training (n=20). Biofeedback sessions were conducted in-clinic and electrical stimulation 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 improvement in frequency of fecal, urine, and gas incontinence, assessed by visual analog scale scores. There were no statistically
significant differences between groups for the primary outcomes. For example, 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.

**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 treatment of urinary incontinence was published in 2015 by Lim et al. Reviewers identified 8 blinded sham-controlled trials (total N=484 patients). Treatment protocols (e.g., 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 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 also not pooled for other outcomes. 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 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 the change in the 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; the difference between groups was statistically significant (p=0.038). 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 2009 sham-controlled randomized trial 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 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 Post Prostatectomy Urinary Incontinence**

One RCT was identified on magnetic stimulation for treating post prostatectomy 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 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 after catheter removal, pad weight was significantly lower in the magnetic stimulation group compared with the control group; and, beginning at 3 months after catheter removal, there were no significant differences 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; also lacking was a placebo effect, which 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 post prostatectomy urinary incontinence. There was a greater improvement in pad weight at 2 months in the magnetic stimulation group than in the pelvic floor muscle exercise 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 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 had mixed findings. Moreover, meta-analyses of RCTs have not found a significant benefit of significant electrical PFS in men with post prostatectomy 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 following factors: low number of trials with short-term follow-up, methodologic limitations, as well as heterogeneity in terms of patient populations, interventions, and outcomes reporting. Only 1 RCT evaluated magnetic stimulation for treating men with post prostatectomy 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.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**American Urological Association**

In 2014, the American Urological Association published guidelines on the diagnosis and management of overactive bladder. Electrical pelvic floor stimulation (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 of urinary incontinence with electrical stimulation using surface electrodes alone, and did not recommend treatment with magnetic stimulation.

**National Institute for Health and Care Excellence**

In 2015, the National Institute for Health and Care Excellence (NICE) issued guidance on the management of urinary incontinence in women. 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.”

In 2007, NICE issued guidance on management of fecal incontinence in adults. (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 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. Electrical PFS was 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.” 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


Document for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE
The following services may be considered investigational.
1.01.17 Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<td>07/31/2015</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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<td>12/01/2016</td>
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<td>10/01/2017</td>
<td>Policy revision without position change</td>
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Definitions of Decision Determinations

**Medically Necessary**: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental**: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation**: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an
authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.