Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

**Section**
1.0 Durable Medical Equipment

**Effective Date**
February 27, 2015

**Original Policy Date**
February 27, 2015

**Next Review Date**
February 2016

**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**

- Sacral Nerve Neuromodulation/Stimulation
- Percutaneous Tibial Nerve Stimulation

**Policy**

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:

- Minnova™ Pelvic Floor Stimulation System
- MyoTrac Infiniti™
- Pathway™ CTS 2000
- NeoControl® Pelvic Floor Therapy System
- EmbaGYN®
- InTone®MV
- BION® device - Pudendal nerve stimulation
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 (when used for pulsed magnetic stimulation for the treatment of incontinence)
- **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**: Incontinence treatment system; pelvic floor stimulator, monitor, sensor and/or trainer

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)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 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 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™ Medical; Brookfield, WI), a nonimplantable device that provides electrical stimulation and/or biofeedback via manometry, was cleared by the FDA. The device is intended for the treatment of male and female urinary and fecal incontinence.

A search of the FDA website in March 2014 did not identify any other nonimplantable electrical stimulators or any magnetic stimulators cleared for treatment of fecal incontinence.

**Literature Review**

The urinary incontinence portion of the policy was based on 2 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessments, both completed in 2000, one on electrical pelvic floor stimulation and the other on magnetic pelvic floor stimulation. (1,2) The assessments stated that accepted outcome measures for evaluating the effectiveness of incontinence treatments include change in number of incontinence episodes and the proportion of patients who become dry or are cured of incontinence. For patients with stress incontinence, the amount of urine loss during a pad test is also considered a valid measure. Another methodologic consideration addressed in the assessments is that, to account for a possible placebo response, studies would ideally be randomized controlled trials (RCTs) that include a sham treatment group. Alternatively, studies could compare pelvic floor stimulation with a treatment known to be effective for treating incontinence, such as pelvic floor exercise.

**Electrical Pelvic Floor Stimulation**

Women with Urinary Incontinence
The 2000 TEC Assessment concluded that there was insufficient evidence that electrical pelvic floor stimulation improved health outcomes compared with placebo or other behavior therapies in women with stress, urge, or mixed incontinence.\(^{(1)}\)

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

Authors of the HTA report 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 study 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 cannot be ruled out. The authors of the systematic review 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 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 an RR of 2.01 (95% CI, 1.28 to 3.15). The AHRQ report concluded that a high level of evidence suggests that electrical stimulation is associated with increased continence rates and improvement in urinary incontinence.

Findings of key RCTs on electrical stimulation for urinary incontinence in women are described in the following section.

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 pelvic floor stimulation, or self-administered behavioral training alone using a self-help booklet.\(^{(5)}\) 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 the groups.

In 2004, Wang et al, in Taiwan compared the outcomes of a 12-week program of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in a randomized study in a group of 103 women with “overactive bladder,” primarily due to urge incontinence.\(^{(6)}\) The biofeedback consisted of an intravaginal electromyographic probe, while an intravaginal electrode provided the electrical stimulation. Treatment outcomes included results of voiding diaries and quality-of-life measures, and urodynamic measures. The authors report that both the biofeedback and electrical stimulation groups reported an increased incidence of resolution or improvement of incontinence but do not describe how this outcome was assessed.
Significant changes were reported in some domains of the quality-of-life questionnaires in the biofeedback and electrical stimulation group, and the improvement in overall quality-of-life score was significantly better for the electrical stimulation group compared with the pelvic floor exercise group. There were no significant differences in the voiding diary scores, but the authors rejected this outcome due to missing data in the diaries.

In 2008, Castro et al in Brazil published an 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.(7) All of the active interventions consisted of 3 sessions a week, which were conducted at a urogynecology clinic under the supervision of a trained physical therapist. The intervention continued for 6 months, at which time outcomes were measured. Outcome assessment was blinded, but patients were not blinded to treatment group and intention-to-treat (ITT) analysis was not used. A total of 118 women were randomized, and 17 (14%) withdrew from the study; the loss of patients was similar in the 4 groups. There were 101 women who completed the study and were included in the analysis. This included 26 women in the pelvic floor muscle training group, 27 in the electrical stimulation group, 24 in the vaginal cones group, and 24 in the untreated group. The primary outcome was the proportion of women with a negative pad test (i.e., less than 2 grams’ weight). 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. Findings in the no-treatment group could be due, at least in part, to a placebo effect. Moreover, the interventions in this study differ from most other studies in that they continued for 6 months and that all sessions were supervised by a trained professional.

Section Summary

Multiple RCTs have been published, mainly before 2001. Meta-analyses have had mixed findings on the impact of electrical intravaginal stimulation on urinary incontinence in women compared with sham treatment.

Men with Postprostatectomy Urinary Incontinence

Several systematic reviews of RCTs have been published. A 2013 Cochrane review by Berghmans et al identified 6 RCTs on electrical stimulation with nonimplanted electrodes for postprostatectomy urinary incontinence in men. The trials varied in the intervention used, the study protocols, the study populations and the 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 of studies evaluating electrical stimulation alone were not pooled.

A 2012 systematic review by Zhu et al had similar findings. This review also evaluated pelvic floor electrical stimulation used to treat postprostatectomy urinary incontinence. The authors identified 4 RCTs with 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 control 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).
A 2012 Cochrane review addressed the more general issue of conservative management of postprostatectomy urinary incontinence. The reviewers identified 3 RCTs evaluating electrical stimulation compared with no stimulation or sham stimulation for postoperative treatment of incontinence. In a pooled analysis, the rate of incontinence at 3 months was lower in the group that received electrical stimulation than in the control group (76% vs 90%, respectively). The pooled risk ratio was 0.84 (95% CI, 0.74 to 0.94). The authors stated that there were too few data to evaluate the long-term impact of electrical stimulation on rates of incontinence.

Representative trials on men with postprostatectomy urinary incontinence are described in the following section:

In 2011, Goode et al published the results of a randomized trial comparing behavioral therapy alone with behavioral therapy in combination with biofeedback and pelvic floor electrical stimulation. 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 one 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 pelvic floor electrical stimulation. 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 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 of 208 (85%) randomized men completed the 8 weeks of treatment. In an ITT 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 significantly 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, and 12/70, 17% in the behavior-plus group) than 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 pelvic floor electrical stimulation. However, the combined intervention of biofeedback and electrical stimulation along with behavioral therapy did not result in better outcomes than behavioral therapy alone.

In 2010, Yamanishi et al published findings of a study comparing electrical stimulation with a sham control group. This trial, conducted in Japan, was a double-blind trial in which 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 12-month study. The continence rate, defined as loss of 8 g 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 several other ways. Differences in the amount (number of grams) of daily leakage were not significantly different between groups at any follow-up time point. For example, after 1 month, the mean amount of leakage was 210 g in the active treatment group and 423 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

There are a few small RCTs evaluating electrical pelvic floor muscle stimulation as a treatment of postprostatectomy urinary incontinence in men. These studies reported improvements on some outcomes with electrical stimulation, but tended to be limited by failure to isolate the effect of electrical simulation and/or lack of a sham comparison or comparison with an accepted treatment. Three pooled analyses of RCTs were identified; 1 did not find a significantly 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.

Individuals with Fecal Incontinence

In 2007, a Cochrane review identified 4 RCTs evaluating electrical stimulation as a treatment of fecal incontinence in adults.(13) 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, and 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.(14) The authors identified 13 RCTs that used 1 or both of these treatments and reported health outcomes (e.g., remission or response rates using validated scales). A pooled analysis of study results did not find a statistically significantly higher rate of remission when electrical stimulation was compared with 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 study included only 2 RCTs on electrical stimulation that were published after the Cochrane review, just described.(15,16) These 2 studies both included the combination of amplitude-modulated medium-frequency stimulation and biofeedback. Electrical stimulation was not evaluated in the absence of biofeedback.

Only 1 sham-controlled RCT has been published on electrical stimulation for fecal incontinence. This study, published by Norton et al in 2006, was conducted in the U.K and included 90 adults.(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 that is hypothesized to have a therapeutic effect. Patients were blinded to treatment group; although nurses who trained patients on device use were not
blinded. The primary outcome was patient self-report of efficacy, using a rating scale ranging from -5 to +5 to indicate symptom change. Seventy of the 90 patients (78%) 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.

Section Summary

Several RCTs have been published evaluating electrical stimulation for treating fecal incontinence. Only 1 of these was sham-controlled, and this study did not find that active stimulation produced better results than sham stimulation. Systematic reviews of RCTs have not found that electrical stimulation was superior to control interventions for treating fecal incontinence.

Magnetic Pelvic Floor Stimulation

Women with Urinary Incontinence

Several RCTs have evaluated magnetic pelvic floor stimulation for treatment of urinary incontinence in women. In 2013, Yamanishi et al in Japan published an industry-sponsored evaluation of magnetic stimulation provided to women with urinary urgency in an armchair-type stimulator.(18) 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 individualized to each patient's maximum tolerable intensity; sham stimulation was set at a lower level than active treatment. Noises differed in the 2 procedures, and patients were isolated from the sounds to maintain blinding. Study personnel were not blinded. A total of 143 of 151 (95%) 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 of incontinence episodes was 13 (SD=11) in the active treatment group compared with 9 (SD=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 RCT evaluating magnetic stimulation using the Neocontrol chair did not find evidence that stimulation improved outcomes. In this study, 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.(19) The study included 70 women, 35 in each group, with stress or mixed urinary incontinence. Treatment in both groups consisted of 3 treatment sessions per week for 6 weeks. There was no significant difference in the active versus sham treatment group in the primary outcome measure, change from baseline in the 20-minute pad test result from baseline 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 outcome analysis.
Medical Policy

There has also been an RCT evaluating magnetic undergarments; these do not appear to be FDA approved for treating urinary incontinence. In 2012, Wallis et al in Australia published a single-blind RCT comparing magnetic progression-free survival with a sham intervention in 122 women at least 60 years old who had urinary incontinence for 6 months or more. Magnetic stimulation was provided via an undergarment that had 15 magnetic disks of 800 to 1200 Gauss each sewn into the cotton bands on the outside of the garment. For the sham intervention, the undergarments were the same, but the magnets were replaced by inert metal disks of the same size and weight. Women were instructed to wear the undergarments at least 6 consecutive hours during the day and at least 6 hours at night. Outcomes were reported after 12 weeks of garment use. A total of 101 of 122 (83%) women completed at least 4 weeks of the intervention and provided data for the efficacy analysis. At 12 weeks, the study did not find any statistically significant differences between groups on any of the efficacy outcomes, which included frequency of incontinence severity and quality-of-life measures. For example, the median change in frequency of incontinence episodes (time period not specified) was 0.75 in the magnetic stimulation group and 0.5 in the sham group (p=0.68).

Section Summary

Several RCTs have evaluated magnetic stimulation for treatment of urinary incontinence in women. Two trials used a chair-style magnetic stimulator and had different findings. The trial that used the FDA-approved Neocontrol chair did not find that magnetic stimulation improved outcomes compared with sham stimulation. The trial that used a Japanese chair product with a magnetic stimulator found better outcomes with active versus sham stimulation on their primary outcome and on some, but not all, secondary outcomes.

Men with Postprostatectomy Urinary Incontinence

One RCT was identified on magnetic stimulation for treating postprostatectomy urinary incontinence. The study was published in 2004 by Yokoyama et al and reported findings from a 3-arm randomized trial from Japan. A total of 36 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 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 no significant differences between groups in quality-of-life measures at any follow-up point.

Individuals with Fecal Incontinence

No studies were identified that evaluated magnetic pelvic floor stimulation as a treatment for fecal incontinence.

Summary

Urinary Incontinence

Findings from multiple RCTs have not found that electrical pelvic floor stimulation 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. There is insufficient evidence on the efficacy of electrical pelvic floor stimulation in the treatment of postprostatectomy incontinence in men, and on the efficacy of magnetic pelvic floor stimulation for treating urinary incontinence in...
Further information on the use of pelvic floor electrical stimulation for the treatment of urinary and fecal incontinence is discussed below.

Men or women. Thus, electrical or magnetic pelvic floor stimulation as a treatment of urinary incontinence is considered investigational.

Fecal Incontinence

Several RCTs have been published evaluating electrical pelvic floor stimulation used to treat fecal incontinence. Only 1 trial was sham-controlled, and this did not find that electrical stimulation improved the net health outcome. Systematic reviews of RCTs have not found that electrical stimulation was superior to control interventions for treating fecal incontinence. No studies were identified on magnetic pelvic floor stimulation for treating fecal incontinence. Thus, electrical or magnetic pelvic floor stimulation as a treatment of fecal incontinence is considered investigational.

Practice Guidelines and Position Statements

In 2012, the European Association of Urology published clinical guidelines on the management of urinary incontinence.(22) The guidelines do not recommend treatment or urinary incontinence with electrical stimulation using surface electrodes alone, and do not recommend treatment with magnetic stimulation.

In October 2006, the National Institute for Health and Clinical Excellence (NICE) issued a guideline on the management of urinary incontinence in women.(23) NICE states that “perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training,” but that “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.” This conclusion regarding use of electrostimulation is based on expert opinion.

In June 2007, NICE issued a guideline on management of fecal incontinence in adults.(24) The document stated that the evidence on electrical stimulation for treatment of fecal incontinence was inconclusive. It recommended that patients who continue to have episodes of fecal incontinence after initial treatment should be considered for specialized management.

Medicare National Coverage

National coverage determination for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)(25) 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.” The document did not mention fecal incontinence.

References


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit 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 are considered investigational and therefore not covered for any indication.

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<th>Type</th>
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<td>E0740</td>
<td>Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer</td>
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<td></td>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
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<td>G0283</td>
<td>Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
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Medical Policy

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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>Policy title change from Urinary Incontinence Outpatient Treatment; BCBSA Medical Policy adoption; Policy revision with 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

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.
For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

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 also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.