



Kansas City

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Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

Policy Number: 1.01.17

Last Review: 2/2014

Origination: 2/2007

Next Review: 2/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for pelvic floor stimulation for the treatment of urinary incontinence. This is considered investigational.

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**.

Description of Procedure or Service

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.

Background

Urinary incontinence is a common condition defined as an involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects quality of life and treatment decisions. The types of urinary incontinence include stress, urge, overflow, functional, and post-prostatectomy incontinence. Nonsurgical treatment options may include pharmacologic treatment, pelvic muscle exercises (PME), bladder training exercises, electrical stimulation, and neuromodulation.

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.

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 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.

Rationale

This policy was created in 1998 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period February 2012 through March 6, 2013.

Literature review

The policy was based on two TEC Assessments, both completed in 2000, one on electrical pelvic floor stimulation (PFS) and the other on magnetic PFS. (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 to 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 to placebo or other behavior therapies in women with stress, urge, or mixed incontinence. (1)

Several more recent systematic reviews have been published. In 2010, the Health Technology Assessment program in the U.K. published a review of studies on non-surgical treatments for women with stress urinary incontinence. (3) The investigators identified 8 RCTs comparing electrical stimulation to no active treatment; a sham control was used in 6 of the studies. 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 to 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 to no active treatment, there was a higher rate of improvement with electrical stimulation (37% versus 14%, OR: 3.93, 95% CI: 1.43 to 10.8). Due to the lack of 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.

In addition, a systematic review of published literature on electrical pelvic floor stimulation was published in 2008. (4) The literature review was funded by the Agency for Healthcare Research and Quality (AHRQ) and conducted by the University of Minnesota Evidence-based Practice Center. The

review included RCTs conducted among women with stress and urge urinary incontinence, overactive bladder with urge incontinence, or minimal urinary incontinence. Study quality was analyzed using the following criteria: participant selection; length and loss of follow-up; use of intention-to treat (ITT) analysis; masking of the treatment status; randomization scheme; adequacy of randomization and allocation concealment; and justification of sample sizes. Results of 12 RCTs did not find that electrical stimulation cured or improved urinary incontinence in women better than sham stimulation or pelvic muscle training. Two of the 12 trials that assessed continence at 6 months or longer follow-up failed to show statistically significant benefit from electrical stimulation compared with continence services or medications. Other RCTs demonstrated no significant benefit of electrical stimulation compared with pelvic floor exercises, biofeedback-assisted training, or placebo.

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

Goode and colleagues 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.

Wang and colleagues, 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 to 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 and colleagues 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 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 (46%) 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.

Conclusions: Findings from multiple RCTs and meta-analyses of RCTs have not found that electrical stimulation used to treat urinary incontinence in women consistently improved the net health outcome compared to placebo or other conservative treatments.

Men with post-prostatectomy urinary incontinence

Two systematic reviews of RCTs were published in 2012. The review by Zhu and colleagues focused on pelvic floor electrical stimulation used to treat post-prostatectomy urinary incontinence. (8) 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 to control within 3 months of prostatectomy (risk ratio [RR]: 1.21; 95% CI: 0.96-1.54). Similarly, a pooled analysis of data from all 4 trials did not show a statistically significant benefit of electrical stimulation on continence levels 6-12 months after prostatectomy (RR: 1.03; 95% CI: 0.88-1.20). The second systematic review was a Cochrane review that addressed the more general issue of conservative management of post-prostatectomy urinary incontinence. (9) The reviewers identified 3 RCTs evaluating electrical stimulation compared to no stimulation or sham stimulation for postoperative treatment of incontinence. In a pooled analysis, the short-term (3-month) rate of incontinence was lower in the group that received electrical stimulation than in the control group (76% vs. 90%, respectively). The pooled risk ratio (RR) 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 post-prostatectomy urinary incontinence are described in the following section:

In 2011, Goode and colleagues published the results of a randomized trial comparing behavioral therapy alone to behavioral therapy in combination with biofeedback and pelvic floor electrical stimulation. (10) 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 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 of 70, 16% in the behavior group and 12 of 70, 17% in the behavior-plus group) than the control group (4 of 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 and colleagues published findings of a study comparing electrical stimulation to a sham control group. (11) This trial, conducted in Japan, was a double-blind trial in which 56 men with severe post-prostatectomy 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 and 25 in the sham group) completed the 12-month study. The continence rate, defined as loss of 8 gm 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 to 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 gm 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 gm in the active treatment group and -257 gm in the sham group, $p<0.01$) but not at the other follow-up time points.

Conclusions: There are a few small RCTs evaluating electrical pelvic floor muscle stimulation as a treatment of post-prostatectomy urinary incontinence in men that report improvements on some outcomes with electrical stimulation. These studies tended to be limited by failure to isolate the effect of electrical stimulation and/or lack of a sham comparison or comparison to an accepted treatment. Two pooled analyses of RCTs were identified; one found short-term benefit of electrical stimulation and the other did not find a statistically significant short- or long-term benefit.

Magnetic Pelvic Floor Stimulation

Women with urinary incontinence

The 2000 TEC Assessment did not identify any RCTs evaluating electromagnetic pelvic floor stimulation for treating adults with incontinence. (2) Several RCTs have subsequently been published. For example, in 2009, Gilling and colleagues in New Zealand published an RCT comparing magnetic stimulation using the Neocontrol chair to a sham treatment. (12) The sham treatment involved inserting a thin aluminum plate in the chair to prevent penetration of the magnetic field. 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.

In 2012, Wallis and colleagues in Australia published a single-blind RCT comparing magnetic progression-free survival (PFS) to a sham intervention in 122 women at least 60 years-old who had urinary incontinence for 6 months or more. (13) Magnetic stimulation was provided via an undergarment that had 15 magnetic disks of 800 to 1,200 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 101/122 (83%) of 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, $p=0.68$. The magnetic undergarments used in this study do not appear to be approved by the FDA for treating urinary incontinence.

Men with post-prostatectomy urinary incontinence

As stated above, the 2000 TEC Assessment did not identify any RCTs evaluating electromagnetic pelvic floor stimulation for treating adults with incontinence. (2) One RCT was identified in literature updates. In 2004, Yokoyama and colleagues reported findings from a 3-arm randomized trial from Japan conducted in men with post-prostatectomy urinary incontinence. (14) A total of 36 men (12 in each group) were randomized to receive extracorporeal magnetic PFS (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 to 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.

Summary

Findings from multiple randomized, controlled trials have not found that electrical pelvic floor stimulation used to treat urinary incontinence in women consistently improved net health outcome compared to placebo or other conservative treatments. Moreover, there is insufficient evidence on the efficacy of electrical pelvic floor stimulation in the treatment of post-prostatectomy incontinence in men, and on the efficacy of magnetic pelvic floor stimulation for treating urinary incontinence in men or women. Thus, pelvic floor stimulation as a treatment of urinary incontinence is considered investigational.

Practice Guidelines and Position Statements

In 2012, the European Association of Urology (EAU) published clinical guidelines on the management of urinary incontinence. (15) The guidelines do not recommend treatment of 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. (16) 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 December 2007, the National Institutes of Health (NIH) convened a Consensus Development Conference, *Prevention of Fecal and Urinary Incontinence* and subsequently released a statement. (17) Included in this statement was the following regarding pelvic floor muscle training and magnetic or electrical stimulation: “Inconsistent low-level evidence from twelve randomized controlled trials did not show that magnetic or electrical stimulation cured or improved urinary incontinence in women better than did sham stimulation or pelvic floor muscle training.”

Medicare National Coverage

National coverage determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8) (18) states “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.”

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Billing Coding/Physician Documentation Information

53899	Unlisted procedure, urinary system
97014	Application of a modality to one or more areas; electrical stimulation (unattended)
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
E0740	Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

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.

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