

Medical Policy Manual

Topic: Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

A variety of non-surgical approaches have been investigated as treatments of urinary incontinence, including pelvic floor muscle exercises (PME), biofeedback and other behavioral therapies, and pelvic floor stimulation. 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 pulsed magnetic innervation. It is thought that pelvic floor stimulation of the pudendal nerve will improve urethral closure by activating the pelvic floor musculature. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. The methods of PFS have varied in location (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, e.g., either detrusor instability, stress incontinence, or a mixed pattern. Magnetic pelvic floor stimulation does not require an internal electrode; patients may sit, fully clothed, on a specialized chair.

Patients receiving PFS may undergo treatments 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 is delivered in the physician's office.

Note: Stimulation of the sacral nerve as a treatment of incontinence is discussed separately in Surgery Policy No. 134.

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 non-implanted 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.

MEDICAL POLICY CRITERIA

Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for urinary incontinence is considered **investigational**.

SCIENTIFIC EVIDENCE

Evidence from randomized controlled trials (RCTs) is needed to establish how electrical and magnetic pelvic stimulation impact health outcomes in patients with urinary incontinence compared with either sham devices or behavioral therapy.

Electrical Pelvic Floor Stimulation

Technology Assessments and Systematic Reviews

Cochrane Review

In 2012, a Cochrane review was published on conservative management of post-prostatectomy urinary incontinence.^[1] Three RCTs were identified that evaluated 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). There were too few data to evaluate the long-term impact of electrical stimulation on rates of incontinence. In addition, one trial was identified on prevention of urinary incontinence after radical prostatectomy; there were insufficient data to pool findings on the preventive use of electrical pelvic floor stimulation.

Meta-analysis

Also in 2012, Zhu and colleagues compared electrical stimulation enhanced pelvic floor muscle training (PFMT) to PFMT alone, as a method for managing post-prostatectomy urinary incontinence.^[2] Four randomized controlled trials with a total of 210 cases were pooled and analyzed. All studies provided data for 6-12 months after surgery. No difference between groups was observed at 3 months or after 6 months of prostatectomy.

BlueCross BlueShield Association (BCBSA) Technology Evaluation Assessment

A 2000 BCBSA Technology Evaluation Center (TEC) assessment reviewed the published peer-reviewed literature focusing on the safety and effectiveness of electrical pelvic floor stimulation compared to placebo and compared to other forms of behavioral therapies, including pelvic floor muscle exercises and the use of vaginal cones.^[3] The specific etiologies of stress incontinence, urge incontinence, and post-prostatectomy incontinence were considered. The assessment offered the following conclusions:

1. Eleven controlled trials, of which all but one were randomized, reported outcomes of pelvic floor stimulation in the treatment of stress incontinence. These trials do not provide strong and consistent evidence that pelvic floor stimulation reduces the frequency and severity of incontinent episodes.
2. Two randomized controlled trials investigated pelvic floor stimulation in women with urge or mixed incontinence. No conclusions can be drawn from either trial. One 1997 trial did not report the key clinical outcomes, i.e., improvement and cure as measured by voiding diaries or pad testing. The second trial found no significant difference between pelvic floor stimulation and the sham treatment arm.
3. One randomized trial focused on pelvic floor stimulation for men with persistent post-prostatectomy incontinence. There was no significant difference in results between the patients receiving pelvic floor stimulation plus pelvic muscle exercises compared to those undergoing muscle exercises alone.

Additional Randomized Controlled Trials

Several additional published RCTs investigated the use of electrical pelvic floor stimulation in patients with stress incontinence, but none provided evidence supporting a beneficial effect of this treatment:

- One small, randomized double-blind study of 27 patients compared a new pattern of electrical stimulation with sham stimulation.^[4] The electrical stimulation group showed statistically greater improvement on the quality of life measure, but no between-group differences were observed in other outcome parameters, including pad testing.
- A randomized trial of 60 women compared the effectiveness of electrical stimulation plus biofeedback with pelvic floor exercise.^[5] The electrical stimulation-biofeedback group performed better than the pelvic floor exercise group. However, the paper did not report key clinical outcomes, e.g., improvement and cure as measured by voiding diaries or pad testing. More importantly, due to the combined therapy of electrical stimulation and biofeedback, the independent effect of electrical stimulation was not evaluated.
- Goode and colleagues reported the outcomes of a randomized trial that randomized 200 women with primary 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.^[6] 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.

- One double-blind randomized controlled study compared the effects of electrical stimulation with sham treatment in 68 patients with urge incontinence due to detrusor overactivity.^[7] Reported outcomes suggested a beneficial treatment effect with electrical stimulation. Based on patient diaries, 19% of patients receiving active treatment versus 3% of patients receiving sham treatment were cured, while 81% of active patients versus 32% of sham patients were improved. These differences were statistically significant. The study did not report the more objective pad testing, and given the inconclusive or conflicting results reported in two earlier studies, additional evidence is needed from well-designed trials to determine the benefits of electrical stimulation for urge incontinence.
- Wang and colleagues 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 of in a group of 103 women with “over active bladder,” primarily due to urge incontinence.^[8] The biofeedback consisted of an intravaginal electromyogram 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. There were significant changes 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 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. Biofeedback was associated with the greatest improvement in muscle strengthening, but as noted above, muscle strength is not considered a key clinical outcome. Pad testing, the most objective outcome was not performed.
- Spruijt and colleagues reported results from a randomized trial involving women over age 65 with symptoms of stress, urge or mixed urinary incontinence.^[9] There were no statistically significant differences between patients treated with electrical stimulation versus those treated with Kegel training only.
- In two separate double-blind studies, symptoms were significantly reduced in both groups following treatment.^[10,11] There were no significant between-group differences in outcomes. Wille and colleagues randomized post-prostatectomy patients to receive 1 of 3 treatments: pelvic muscle exercises (PMEs), PME plus electrical stimulation, or PME in conjunction with both electrical stimulation and biofeedback.^[12] Outcomes were evaluated according to questionnaires and the more objective pad t^{est}. There were no statistically significant differences in continence rates between the three groups.
- A randomized, controlled trial conducted in the United Kingdom^[13] evaluated the efficacy of neuromuscular electrical stimulation in addition to electromyographic biofeedback and pelvic floor muscle training in multiple sclerosis patients (n=74) with lower urinary tract dysfunction. The intervention period was for 9 weeks, with a follow-up at 16 and 24 weeks. The primary outcome measure was the number of leakage episodes. At the end of the active treatment period of 9 weeks, the mean number of incontinence episodes was reduced in both groups (active treatment by 85% and placebo by 47%) and there was a statistically superior benefit in active treatment group when compared to placebo (p=0.0028). However, this significant difference was not maintained at weeks 16 and 24. Active treatment group demonstrated statistically significant

improvement in the Visual Analogue Scale of Bothersomeness (the secondary outcome) at weeks 9 and 24.

- A small randomized trial evaluated safety and efficacy of transcutaneous interferential (IF) electrostimulation on voiding symptoms and urodynamic variables in 30 children with myelomeningocele (MMC)-induced refractory neurogenic detrusor overactivity.^[14] The participants underwent urodynamic study (UDS) before and after IF and at 6 month follow-up. The study reported significant improvements in the UDS parameters immediately after IF treatment in the active treatment group. 78% patients gained continence immediately after IF therapy and 60% had persistent continence at 6 months in the active treatment group.
- A small randomized trial analyzed the benefit of the early combined use of functional pelvic floor electrical stimulation (ES) and biofeedback in terms of time to recovery and rate of continence after radical prostatectomy in 60 patients.^[15] The evaluation of continence was performed at time 0, at 2 and 4 weeks, and at 2, 3, 4, 5 and 6 months. The study reported a significant difference ($p < 0.05$) between active treatment (biofeedback and ES) and control (biofeedback only) groups in % of continent patients from 4 weeks (63.3% group 1 and 30.0% group 2) to 6 months (96.7% group 1 and 66.7% group 2).
- In the randomized trial, published in 2010 by Yamanishi and colleagues, electrical stimulation was compared to a sham-control group.^[16] 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. 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 one 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.
- In 2010, 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.^[17] 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%) of 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 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.

Magnetic Pelvic Floor Stimulation

Technology Assessments

- The 2000 BCBSA TEC Assessment evaluated the use of electromagnetic pelvic floor stimulation.^[18] At the time, minimal data regarding these devices were available, and no randomized trials had isolated and validated the effectiveness of the treatment.^[19,20] Galloway and colleagues presented the results of a multicenter prospective nonrandomized trial in 83 patients with stress urinary incontinence.^[21] Patients were treated for 20 minutes twice a week for six weeks. A total of 66% of patients were either dry or using no more than one pad per day after a 3-month follow-up. The TEC Assessment concluded that these preliminary results require confirmation in randomized trials.

Randomized Controlled Trials

- A study of 52 patients randomized to either active or sham magnetic stimulation reported statistically significant differences between baseline and post treatment measures in the active functional magnetic stimulation group.^[22] However, p values were not reported for comparisons between the placebo and treatment groups. Thus, it is not possible to reach scientific conclusions from this study concerning the effects of functional magnetic stimulation on health outcomes.
- Another randomized, double-blind, sham controlled study of 39 patients reported significant improvement between baseline and post treatment measures in both the active and sham groups at 24 weeks follow-up.^[23] The between group comparison was not statistically significant.
- In another study, Galloway and colleagues reported an update of the multicenter prospective nonrandomized trial that included 111 women with stress urinary incontinence who were treated with extracorporeal magnetic innervation.^[24] A total of 47 women completed 6-month follow-up testing; 38 patients were completely dry or used less than 1 pad per day (81%). Pad use was reduced in 33 patients (70%). Nevertheless, lacking a control group, the influence of patient selection bias on these outcomes cannot be ruled out.
- Fujishiro and colleagues published the results of a trial that enrolled 37 women with frequency or urge incontinence to receive either true or placebo magnetic stimulation.^[25] Outcomes were assessed at 3 days and 1 week after treatment. The authors reported the treatment group reported improvement in the urine volume, number of leaks, and quality of life. However, the short follow-up of 1 week precludes scientific conclusions.

- Voorham-van der Zalm and colleagues reported no significant difference in before and after treatment outcomes in 74 patients who received eight weeks of magnetic stimulation treatment.^[26]
- Yokoyama and colleagues reported findings from a 3-arm randomized trial from Japan conducted in men with post-prostatectomy urinary incontinence.^[27] A total of 36 men (12 in each group) were randomized to receive extracorporeal magnetic pelvic floor 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 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.
- One randomized trial compared the efficacy of extracorporeal electromagnetic stimulation (ES) of the pelvic floor with sham ES in 70 women with urodynamically confirmed stress urinary incontinence (SUI).^[28] The trial reports that overall, the ES was no more effective than sham treatment. In those women who were unable to generate adequate pelvic floor muscle contractions, there was an objective improvement in provocative pad testing when compared to sham treatment. However, this trial was too small to reliably measure the difference in the outcomes of interest. The small study population limits the ability to rule out the role of chance as an explanation of findings. In addition, the study had a short follow-up time (6 months) limiting conclusions regarding the durability of the treatment effects.
- Wallis and colleagues published a single-blind RCT comparing magnetic PFS to a sham intervention in 122 women at least 60-years-old who had urinary incontinence for 6 months or more.^[29] 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.

Clinical Practice Guidelines

No clinical practice guidelines could be identified which recommend the use of electrical or magnetic pelvic floor stimulation as a method for treating urinary incontinence.

Summary

The randomized trials of electrical and magnetic pelvic stimulation described in this policy have significant methodological limitations and cannot reliably demonstrate that pelvic floor stimulation results in improved health outcomes in patients with urinary incontinence when compared to either sham devices or behavioral therapy. The limitations include, but are not limited to the following:

- Small study populations, which limit the ability to rule out the role of chance as an explanation of findings.
- Short follow-up times, which limit conclusions regarding the durability of any treatment effects.

Therefore, pelvic floor stimulation using either electrical or magnetic stimulation of the pelvic floor muscles is considered investigational as a treatment for urinary incontinence.

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CROSS REFERENCES

[Electrical Stimulation Devices Index](#), Durable Medical Equipment, Policy No. 83

[Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence](#), Surgery, Policy No. 130

[Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction](#), Surgery Policy No. 134

[Posterior Tibial Nerve Stimulation for Voiding Dysfunction](#), Surgery Policy No. 154

CODES	NUMBER	DESCRIPTION
There is no specific code for the administration of pelvic floor stimulation.		
CPT	53899	Unlisted procedure, urinary system
	97014	Electrical stimulation (unattended)
	97032	Application of modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	E0740	Incontinence treatment system; pelvic floor stimulator, monitor, sensor and/or trainer