

## ***Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence***

**Effective:** February 1, 2019

**Next Review:** October 2019

**Last Review:** January 2019

### **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**

Pelvic floor stimulation (PFS) involves either electrical stimulation of pelvic floor muscles using a probe wired to a device for controlling the electrical stimulation, or more recently, extracorporeal pulsed magnetic innervation. Electrical stimulation of the pelvic floor has also been proposed as a treatment of urinary and fecal incontinence.

### **MEDICAL POLICY CRITERIA**

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

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

1. [Electrical Stimulation Devices Index](#), Durable Medical Equipment, Policy No. 83
2. [Transanal Radiofrequency Treatment of Fecal Incontinence](#), Surgery, Policy No. 129
3. [Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction](#), Surgery, Policy No. 134

## BACKGROUND

A variety of nonsurgical approaches have been investigated as treatments of urinary or fecal incontinence, including pelvic floor muscle exercises (PME), biofeedback and other behavioral therapies, and pelvic floor stimulation (PFS). It is thought that 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 the following: 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 etiology of incontinence (e.g., detrusor instability, stress incontinence, mixed pattern). Magnetic PFS does not require an internal electrode; patients may sit, fully clothed, on a specialized chair.

Patients receiving electrical PFS may undergo treatments in a physician's or physical therapy office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS is delivered in the physician's office.

## REGULATORY STATUS

Several electrical stimulators have been cleared by the U.S. Food and Drug Administration (FDA). In 2006, the MyoTrac Infiniti™ (Thought Technology) and in 2015, the ApexM (InControl Medical), nonimplanted electrical stimulators for treating urinary incontinence, were 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). In 2011, the itouch Sure Pelvic Floor Exerciser (TensCare) was cleared for marketing. This product is being marketed in the United States as EmbaGYN® (Everett Laboratories).

In 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus) was approved by 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 2014, the InTone®MV (InControl Medical), a nonimplantable device that provides electrical stimulation and/or biofeedback via manometry, was cleared by FDA. The device is intended to treat male and female urinary and fecal incontinence.

FDA product code: KPI.

**Note:** Stimulation of the sacral nerve or the posterior tibial nerve as a treatment of incontinence is discussed in separate medical policies. See Cross References.

## EVIDENCE SUMMARY

Evidence from randomized controlled trials (RCTs) is needed to establish how electrical and magnetic pelvic stimulation impact health outcomes in patients with urinary or fecal

incontinence compared to either sham devices or behavioral therapy.

## **ELECTRICAL PELVIC FLOOR STIMULATION**

### **Urinary Incontinence in Women**

#### Systematic Reviews

In 2016, Moroni published a systematic review of conservative treatment of stress urinary incontinence.<sup>[1]</sup> Five trials (total N=221 women) were identified comparing intravaginal electrical stimulation versus control. There were insufficient data on cure rates (e.g., continence rates). A pooled analysis of four studies reporting urine quantity with a pad weight test found significantly greater reduction in pad weight in the treatment versus control groups (mean difference [MD], -9.15; 95% CI, -17.22 to -1.08). A pooled analysis of two studies found significantly greater improvement in incontinence-specific quality of life (QOL) in the electrical PFS group than in the control group (MD = -1.44; 95% CI, -1.94 to -0.95). Three studies were included in a pooled analysis of number of incontinence episodes; findings of this meta-analysis were not reported. The reviewers stated that, among all conservative treatments assessed, evidence was strongest in support of pelvic floor muscle training, with or without biofeedback, for treatment of stress urinary incontinence.

In 2012, the Agency for Healthcare Research and Quality (AHRQ) conducted a comparative effectiveness systematic review of nonsurgical treatments for urinary incontinence (UI) in adult women.<sup>[2]</sup> The primary therapeutic outcomes for review were rates of continence, improvements in UI, and harms. Nine studies were identified that evaluated intravaginal electrical stimulation in women with urgency UI, stress UI, or mixed UI. Eight of the nine studies were published in 2000 or earlier; nearly all used a sham treatment as the control condition. The studies differed in the stimulation frequencies used (4 to 50 Hz.) and the duration of therapy (4 to 15 weeks). A pooled analysis of continence rates in eight RCTs comparing electrical stimulation with no active treatment yielded a relative risk (RR) of 2.86 (95% CI, 1.57 to 5.23) in favor of the active treatment group. The rate of continence with electrical stimulation (23%) was comparable to the rates for pelvic floor muscle training (PFMT) (38%) and for PFMT combined with bladder training (21%). A pooled analysis of improvement in incontinence symptoms yielded a RR of 2.01 (95% CI, 1.28 to 3.15) in favor of the active stimulation group. 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. However, this conclusion appears to include data for sacral nerve and posterior tibial nerve stimulation in addition to pelvic floor stimulation.

#### Randomized Controlled Trial (RCT)

RCTs published since the AHRQ comparative effectiveness report are summarized here.

Elmelund (2018) published an investigator-blinded RCT evaluating pelvic floor muscle training (PMFT) alone or in combination with intravaginal electrical stimulation (IVES) for urinary incontinence in women with incomplete spinal cord injury.<sup>[3]</sup> Thirty-six women were randomly assigned to either PFMT (N = 17) or PFMT+IVES (N = 19); 27 completed the interventions (N = 17 and 19, respectively). At 12 and 24 weeks follow-up there were no differences between the groups on the International Consultation on Incontinence Questionnaire urinary incontinence short form (ICIQ-UI-SF) or episodes of urinary incontinence. At 12 weeks, only

the PFMT group had a significant change from baseline on ICIQ-UI-SF (-2.4 [95% CI -4.3 - -0.5]) and daily episodes of urinary incontinence (-0.4 [95% CI -0.8 - -0.1]).

In 2015, Abdelbary published a three-group RCT in women with overactive bladder comparing electrical PFS, local vaginal estrogen treatment, and a combination of both interventions.<sup>[4]</sup> The trial included 315 women, 105 per group. Electrical stimulation was administered using a vaginal probe. At six-month followup, there were statistically significant differences among the three groups in outcomes that included the number of voids per day, the number of incontinence episodes, the number of urgency episodes, and the QOL score ( $p < 0.001$  for each outcome). In a post hoc analysis, improvement was better in the electrical PFS group than in the estrogen-only group for all key variables. The combined treatment group had better results than the estrogen-only group on several outcomes, but not voiding frequency per day, the number of incontinence episodes, or QOL.

In 2014, Moroni reported results from an RCT wherein 45 women with stress UI were randomized to one of three groups, surface electrical stimulation (SES), intravaginal electrical stimulation (IVES), or no treatment (control).<sup>[5]</sup> Each group included 15 women. Both treatment groups reported significant improvement in urinary loss, contraction pressure, reduction in incontinence impact and limitations of daily activities, and improvement in sleep, physical limitation, emotion, and disposition. Pelvic floor muscle strength increased only in the IVES group. The authors noted that this study was preliminary and limited by the absence of electromyographic and ultrasonographic evaluation for changes in the pelvic floor muscles after electrical stimulation. Further studies were recommended that included these measurements along with longer follow-up.

### 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.

## **Urinary Incontinence in Men**

### Systematic Reviews

Kannan (2018) published a systematic review and meta-analysis evaluating pelvic floor muscle training (PFMT) alone and in combination with biofeedback (BFB), electrical stimulation (ES), or both for urinary incontinence in men following prostatectomy.<sup>[6]</sup> Publications were identified through August 2017, selected according to PRISMA guidelines, and rated for quality of evidence according to the GRADE system. Fifteen studies (N = 3503, aged 45 to 90) were included for analysis. RCTs, pilot RCTs, and randomized cluster and crossover trials, published in English and Chinese languages were included. Sample sizes in the included studies ranged from 16 to 203 men. Eight of the 15 studies concealed allocation; four masked the assessors, and one masked the participants. Only two studies were evaluated in pooled analysis for PFMT plus ES as compared to no-treatment control and sham ES. Fewer grams of urine were lost (via 24-hour pad test) in the PFMT plus ES group as compared to the no-treatment control immediately following intervention. Although the results were statistically significant, according to the authors the volume of urine lost was clinically trivial. The authors also pointed out that ES is contraindicated in those with a history of malignancy, due to the risk of stimulation cancer cells into further proliferation.

A 2013 Cochrane systematic review by Berghmans identified six RCTs on electrical stimulation with nonimplanted electrodes for postprostatectomy urinary incontinence in men.<sup>[7]</sup> The trials varied in the intervention used, the study protocols, the study populations and the outcome measures. In a pooled analysis of four 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 three months (RR=0.93; 95% CI, 0.82 to 1.06). Findings of studies evaluating electrical stimulation alone were not pooled.

In 2012, a Cochrane systematic review was published on the more general issue of conservative management of postprostatectomy urinary incontinence.<sup>[8]</sup> Three RCTs<sup>[9-11]</sup> 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 (three-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.

Also in 2012, Zhu compared electrical stimulation enhanced pelvic floor muscle training (PFMT) to PFMT alone, as a method for managing post-prostatectomy urinary incontinence.<sup>[12]</sup> Four RCTs<sup>[9,10,13,14]</sup> 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 three months or after six months of prostatectomy. The authors noted a number of limitations to this meta-analysis such as the uncertain quality of the included studies due to lack of description of randomization concealment and blinding techniques. In addition, there was variability among treatment regimens (i.e., type and duration of stimulation, and intensity of training) and outcomes measurements. Finally, there were variations in the patient populations, with some studies applying postoperative interventions to all men (i.e., prevention) while other studies included only men with confirmed UI (i.e., treatment).

### Randomized Controlled Trials (RCTs)

No new RCTs were identified since the above systematic reviews were published.

### 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 stimulation and/or lack of a sham comparison or comparison with an accepted treatment. Three pooled analyses of RCTs were identified; one 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.

## **Fecal Incontinence**

### Systematic Review

In 2007, a Cochrane systematic review identified four RCTS evaluating electrical stimulation as a treatment of fecal incontinence in adults.<sup>[15]</sup> One RCT was sham-controlled<sup>[16]</sup>, one compared electrical stimulation with levatorplasty<sup>[17]</sup>, and two used electrical stimulation as an adjunct treatment<sup>[18,19]</sup>. The Cochrane investigators concluded that there is insufficient evidence to draw conclusions on efficacy or to establish patient selection criteria for electrical stimulation for treating fecal incontinence. Methodological limitations in the four included RCTS included small sample size, short-term followup, large loss-to-followup in some studies, within-study differences between treatment and control groups in adjunctive therapies that could impact outcomes, and the lack of a sham control group in three of the four RCTS.

A 2013 systematic review by Vonthein searched for studies on the impact of biofeedback and/or electrical stimulation for treating fecal incontinence in adults.<sup>[20]</sup> The authors identified 13 RCTS that reported the health outcomes (e.g., remission or response rates using validated scales) of one or both of these treatments. 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 review included only two RCTS<sup>[21,22]</sup> on electrical stimulation that were published after the 2007 Cochrane review summarized above. Both RCTS included the combination of amplitude-modulated medium-frequency stimulation and biofeedback. Electrical stimulation was not evaluated in the absence of biofeedback.

### Randomized Controlled Trials (RCTs)

In 2015 Cohen-Zubary published a study which randomized 42 women with fecal incontinence to six weeks of electrical stimulation (n=22) or biofeedback training (n=20).<sup>[23]</sup> Biofeedback sessions were conducted in-clinic and electrical stimulation sessions occurred in the home following an initial training in-clinic. A total of 36 women (86%) completed the study and were included in the analysis; the analysis was not ITT. The study's primary end points were improvement in frequency of fecal, urine, and gas incontinence, assessed by VAS scores. There were no statistically significant differences between groups in the primary study outcomes. For example, the mean VAS for solid stool incontinence at baseline in the electrical stimulation group was 2.9±2.8, and this decreased to 0.9±0.9 at follow-up. In the biofeedback group, the baseline VAS was 1.1±2.1 and 0.3±0.5 at follow-up. The p value for the between-group differences in this outcome was not statistically significant. For within-group changes, the electrical stimulation group improved significantly on solid stool incontinence but not liquid stool or gas incontinence, and the biofeedback group did not improve significantly on any of the fecal incontinence outcomes.

### Section Summary

Several RCTS have been published evaluating electrical stimulation for treating fecal incontinence. Only one 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**

## Urinary Incontinence in Women

### Systematic Review

In a literature search through December 30, 2011, the 2012 AHRQ comparative effectiveness systematic review<sup>[2]</sup> identified five RCTs that compared active to sham magnetic stimulation in women with UI<sup>[24]</sup>, stress UI<sup>[25,26]</sup>, mixed<sup>[26]</sup> or predominant urgency UI<sup>[27]</sup>. The two outcomes reported were the rate of continence and improvement in UI. Adverse effects were not reported. The RCTs differed in the stimulation frequencies used (10, 15, or 18.5 Hz.) and the duration of therapy (one to eight weeks). Only one RCT<sup>[24]</sup> reported increased continence rates. Pooled analysis demonstrated no significant increase in rate of continence between active and sham stimulation. For improvement in UI, two<sup>[24,25]</sup> of the three<sup>[24,25,27]</sup> studies that examined this outcome reported positive results with active magnetic stimulation compared to sham stimulation; pooled analysis demonstrated a 130% relative improvement in UI in the active stimulation group. Improved quality of life was reported in one<sup>[28]</sup> of the two<sup>[26,28]</sup> RCTs. The authors concluded that, for stress UI, low-level evidence showed improved quality of life, while moderate-level evidence showed no increase in urinary continence rates with active compared to sham magnetic stimulation.

In 2015, a systematic review of RCTs on magnetic stimulation for treatment of urinary incontinence was published by Lim<sup>[29]</sup>. The reviewers identified eight 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 one trial reported this outcome, so data were not pooled. A meta-analysis of three studies reporting improvement in the continence rate found significantly greater improvement in the treatment versus sham group (RR=2.29; 95% CI, 1.60 to 3.29). Due to the variability across trials in types of incontinence treated and/or outcome reporting, data were also not pooled for other outcomes. The reviewers noted that the evidence was limited by low quality trials with short-term follow-up.

### Randomized Controlled Trials

Lim (2018) published results from a double-blind, sham-controlled RCT evaluating patient perception and satisfaction with pulsed magnetic stimulation (PMS) for the treatment of female stress urinary incontinence (SUI) in 115 patients (active: n = 57, sham: n = 58).<sup>[30]</sup> Patients were randomized to receive active or sham PMS twice per week, for 8 weeks. Perception and acceptability were not different between groups by any measure. Patient satisfaction was higher in the active group than the sham group, and also the percentage of patients who much or very better, as measured using the PGI-I. Adverse events did not differ between groups.

Yamanishi (2017) evaluated the effect of magnetic stimulation on urodynamic stress incontinence in patients who had not been cured by pelvic floor muscle training.<sup>[31]</sup> Female patients were randomly assigned to either magnetic treatment (18 patients) or sham control (12 patients) groups. There was statistically significant improvement for the active treatment group but not the sham group in the number of incontinence episodes per week, the degree of incontinence (in g/day; determined using the pad test), the total score on the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), the ICIQ quality of life (QOL) score, and the abdominal leak point pressure (ALPP) on urodynamic study. The only significant intergroup difference was in the changes from baseline in the ICIQ-SF and ALPP. There were no treatment-related adverse events reported.

A double blind RCT with a sham control testing the efficacy of pulsed magnetic stimulation for female stress urinary incontinence was published in 2017 by Lim.<sup>[32]</sup> One hundred and twenty patients received pulsed magnetic stimulation or sham treatment for two months. After that initial period, all patients were given the option of another two months of treatment. Responses were measured as a five-point reduction in the International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form score. After two months of treatment, groups were statistically significantly different, with 75% of the active treatment group and 21.7% of the sham treatment group responding. 40% of the active treatment group and 68% of the sham treatment group elected to continue treatment for another two months. At 14 months, treatment groups had statistically significant differences. 75% of subjects who received four months of active treatment, 68.3% of those who received two months of active treatment, and 21.1.5 of those who received sham treatment were responders.

A single-blind RCT by Wallis (2012), not included in the systematic reviews above, compared magnetic PFS to a sham intervention in 122 women at least 60-years-old who had urinary incontinence for six months or more.<sup>[33]</sup> 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 six consecutive hours during the day and at least six hours at night. Outcomes were reported after 12 weeks of garment use. A total of 101/122 (83%) of women completed at least four 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 using magnetic chairs or undergarments for treatment of urinary incontinence in women. Pooled analysis demonstrated no significant increase in rate of continence between active and sham stimulation. The evidence was insufficient to reach conclusions about the efficacy of these modalities due to methodological limitations in the included studies. These limitations included heterogeneity in the types of UI being treated and the treatment protocols, and the lack of long-term followup data. Further data are needed from large, long-term, sham-controlled RCTs.

## **Urinary Incontinence in Men**

### Systematic Review

The 2012 Cochrane systematic review reported insufficient evidence to determine the effect of postprostatectomy extracorporeal magnetic innervation delivered using a magnetic chair for the treatment or prevention of postprostatectomy UI.<sup>[8]</sup> The RCTs included in the review had significant methodological limitations which included small sample size, lack of long-term followup, and insufficient descriptions of randomization method, allocation concealment, and blinding.

### Randomized Controlled Trials



No new RCTs were identified since the above systematic reviews were published.

### Section Summary

Few RCTs have been published for magnetic stimulation for treating fecal incontinence. The systematic review of RCTs reported that numerous methodological limitations in the RCTs limited interpretation of results and were unable to reach conclusions about the effectiveness of magnetic innervation to control postprostatectomy urinary incontinence.

### **Fecal Incontinence**

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

## **PRACTICE GUIDELINE SUMMARY**

### **AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS**

The 2015 American Congress of Obstetricians and Gynecologists (ACOG) practice bulletin on treatment of urinary incontinence in women indicated electrical stimulation may be used to augment pelvic muscle exercises; however, the bulletin noted that, “the addition of pelvic floor electrical stimulation did not result in significantly greater improvement than behavioral training alone.”<sup>[34]</sup> In addition, ACOG noted, “pelvic muscle exercise appears to be superior to electrical stimulation and vaginal cones in the treatment of stress incontinence.”

### **AMERICAN UROLOGICAL ASSOCIATION AND THE SOCIETY OF URODYNAMICS, FEMALE PELVIC MEDICINE & UROGENITAL RECONSTRUCTION (AUA/SUFU)**

The 2014 evidence-based practice guidelines recommended offering behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training) as first line therapy to all patients with overactive bladder.<sup>[35]</sup> The list of components for behavioral therapies included electrical stimulation, though the type and site of stimulation were not specified. This recommendation was rated as a Standard, defined as a directive statement that an action should or should not be taken based on Grade A (high quality; high certainty) or B (moderate quality; moderate certainty) evidence. For this recommendation, the strength of evidence was rated as Grade B.

Magnetic stimulation was not addressed in this guideline.

## **SUMMARY**

There is not enough research to show that electrical or magnetic pelvic floor stimulation improves health outcomes for people with urinary or fecal incontinence. More research is needed to know how well electrical or magnetic pelvic floor stimulation works for incontinence. Therefore, use of either electrical or magnetic stimulation of the pelvic floor muscles is considered investigational as a treatment for urinary or fecal incontinence.

## **REFERENCES**

1. Moroni, RM, Magnani, PS, Haddad, JM, Castro Rde, A, Brito, LG. Conservative Treatment of Stress Urinary Incontinence: A Systematic Review with Meta-analysis of Randomized Controlled Trials. *Revista brasileira de ginecologia e obstetricia : revista da Federacao Brasileira das Sociedades de Ginecologia e Obstetricia*. 2016 Feb;38(2):97-111. PMID: 26883864
2. Shamliyan T, Wyman J, Kane RL et al. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Comparative Effectiveness Review No. 36. (Prepared by the University of Minnesota Evidence-based Practice Center under Contract No. HHS 290-2007-10064-I.). 2012. [cited 10/25/2017]; Available from: <https://effectivehealthcare.ahrq.gov/topics/urinary-incontinence-treatment/research/>
3. Elmelund, M, Biering-Sorensen, F, Due, U, Klarskov, N. The effect of pelvic floor muscle training and intravaginal electrical stimulation on urinary incontinence in women with incomplete spinal cord injury: an investigator-blinded parallel randomized clinical trial. *International urogynecology journal*. 2018 Nov;29(11):1597-606. PMID: 29574482
4. Abdelbary, AM, El-Dessoukey, AA, Massoud, AM, et al. Combined Vaginal Pelvic Floor Electrical Stimulation (PFS) and Local Vaginal Estrogen for Treatment of Overactive Bladder (OAB) in Perimenopausal Females. Randomized Controlled Trial (RCT). *Urology*. 2015 Sep;86(3):482-6. PMID: 26135813
5. Correia, GN, Pereira, VS, Hirakawa, HS, Driusso, P. Effects of surface and intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: randomized controlled trial. *European journal of obstetrics, gynecology, and reproductive biology*. 2014 Feb;173:113-8. PMID: 24382548
6. Kannan, P, Winser, SJ, Fung, B, Cheing, G. Effectiveness of Pelvic Floor Muscle Training Alone and in Combination With Biofeedback, Electrical Stimulation, or Both Compared to Control for Urinary Incontinence in Men Following Prostatectomy: Systematic Review and Meta-Analysis. *Physical therapy*. 2018 Nov 1;98(11):932-45. PMID: 30137629
7. Berghmans, B, Hendriks, E, Bernards, A, de Bie, R, Omar, MI. Electrical stimulation with non-implanted electrodes for urinary incontinence in men. *The Cochrane database of systematic reviews*. 2013;6:CD001202. PMID: 23740763
8. Campbell, SE, Glazener, CM, Hunter, KF, Cody, JD, Moore, KN. Conservative management for postprostatectomy urinary incontinence. *The Cochrane database of systematic reviews*. 2012;1:CD001843. PMID: 22258946
9. Wille, S, Sobottka, A, Heidenreich, A, Hofmann, R. Pelvic floor exercises, electrical stimulation and biofeedback after radical prostatectomy: results of a prospective randomized trial. *J Urol*. 2003 Aug;170(2 Pt 1):490-3. PMID: 12853806
10. Yamanishi, T, Mizuno, T, Watanabe, M, Honda, M, Yoshida, K. Randomized, placebo controlled study of electrical stimulation with pelvic floor muscle training for severe urinary incontinence after radical prostatectomy. *J Urol*. 2010 Nov;184(5):2007-12. PMID: 20850831
11. Hoffmann, W, Liedke, S, Dombo, O, Otto, U. Electrical stimulation to treat postoperative incontinence: Therapeutic benefit in regard to quality of life. *Urologe*. 2004;44:33040. PMID: No PMID Entry
12. Zhu, YP, Yao, XD, Zhang, SL, Dai, B, Ye, DW. Pelvic floor electrical stimulation for postprostatectomy urinary incontinence: a meta-analysis. *Urology*. 2012 Mar;79(3):552-5. PMID: 22386394
13. Yokoyama, T, Nishiguchi, J, Watanabe, T, et al. Comparative study of effects of extracorporeal magnetic innervation versus electrical stimulation for urinary

- incontinence after radical prostatectomy. *Urology*. 2004 Feb;63(2):264-7. PMID: 14972468
14. Moore, KN, Griffiths, D, Hughton, A. Urinary incontinence after radical prostatectomy: a randomized controlled trial comparing pelvic muscle exercises with or without electrical stimulation. *BJU international*. 1999 Jan;83(1):57-65. PMID: 10233453
  15. Hosker, G, Cody, JD, Norton, CC. Electrical stimulation for faecal incontinence in adults. *The Cochrane database of systematic reviews*. 2007(3):CD001310. PMID: 17636665
  16. Norton, C, Gibbs, A, Kamm, MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. *Diseases of the colon and rectum*. 2006 Feb;49(2):190-6. PMID: 16362803
  17. Osterberg, A, Edebol Eeg-Olofsson, K, Hallden, M, Graf, W. Randomized clinical trial comparing conservative and surgical treatment of neurogenic faecal incontinence. *The British journal of surgery*. 2004 Sep;91(9):1131-7. PMID: 15449263
  18. Fynes, MM, Marshall, K, Cassidy, M, et al. A prospective, randomized study comparing the effect of augmented biofeedback with sensory biofeedback alone on fecal incontinence after obstetric trauma. *Diseases of the colon and rectum*. 1999 Jun;42(6):753-8; discussion 8-61. PMID: 10378599
  19. Mahony, RT, Malone, PA, Nalty, J, Behan, M, O'Connell P, R, O'Herlihy, C. Randomized clinical trial of intra-anal electromyographic biofeedback physiotherapy with intra-anal electromyographic biofeedback augmented with electrical stimulation of the anal sphincter in the early treatment of postpartum fecal incontinence. *American journal of obstetrics and gynecology*. 2004 Sep;191(3):885-90. PMID: 15467559
  20. Vonthein, R, Heimerl, T, Schwandner, T, Ziegler, A. Electrical stimulation and biofeedback for the treatment of fecal incontinence: a systematic review. *International journal of colorectal disease*. 2013 Nov;28(11):1567-77. PMID: 23900652
  21. Schwandner, T, Konig, IR, Heimerl, T, et al. Triple target treatment (3T) is more effective than biofeedback alone for anal incontinence: the 3T-AI study. *Diseases of the colon and rectum*. 2010;53:1007-16. PMID: 20551752
  22. Schwandner, T, Hemmelmann, C, Heimerl, T, et al. Triple-target treatment versus low-frequency electrostimulation for anal incontinence: a randomized, controlled trial. *Deutsches Arzteblatt international*. 2011 Sep;108(39):653-60. PMID: 22013492
  23. Cohen-Zubary, N, Gingold-Belfer, R, Lambort, I, et al. Home electrical stimulation for women with fecal incontinence: a preliminary randomized controlled trial. *International journal of colorectal disease*. 2015 Apr;30(4):521-8. PMID: 25619464
  24. But, I. Conservative treatment of female urinary incontinence with functional magnetic stimulation. *Urology*. 2003 Mar;61(3):558-61. PMID: 12639647
  25. Fujishiro, T, Enomoto, H, Ugawa, Y, Takahashi, S, Ueno, S, Kitamura, T. Magnetic stimulation of the sacral roots for the treatment of stress incontinence: an investigational study and placebo controlled trial. *J Urol*. 2000 Oct;164(4):1277-9. PMID: 10992380
  26. Manganotti, P, Zaina, F, Vedovi, E, et al. Repetitive magnetic stimulation of the sacral roots for the treatment of stress incontinence: a brief report. *Europa medicophysica*. 2007 Sep;43(3):339-44. PMID: 17259914
  27. But, I, Faganelj, M, Sostaric, A. Functional magnetic stimulation for mixed urinary incontinence. *J Urol*. 2005 May;173(5):1644-6. PMID: 15821527
  28. Gilling, PJ, Wilson, LC, Westenberg, AM, et al. A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs sham therapy in the treatment of women with stress urinary incontinence. *BJU international*. 2009 May;103(10):1386-90. PMID: 19154474

29. Lim, R, Lee, SW, Tan, PY, Liong, ML, Yuen, KH. Efficacy of electromagnetic therapy for urinary incontinence: A systematic review. *Neurourology and urodynamics*. 2015 Nov;34(8):713-22. PMID: 25251335
30. Lim, R, Liong, ML, Leong, WS, Khan, NAK, Yuen, KH. Patients' perception and satisfaction with pulsed magnetic stimulation for treatment of female stress urinary incontinence. *International urogynecology journal*. 2018 Jul;29(7):997-1004. PMID: 28744557
31. Yamanishi, T, Suzuki, T, Sato, R, Kaga, K, Kaga, M, Fuse, M. Effects of magnetic stimulation on urodynamic stress incontinence refractory to pelvic floor muscle training in a randomized sham-controlled study. *Lower urinary tract symptoms*. 2017 Sep 29. PMID: 28961380
32. Lim, R, Liong, ML, Leong, WS, Karim Khan, NA, Yuen, KH. Pulsed Magnetic Stimulation for Stress Urinary Incontinence: 1-Year Followup Results. *J Urol*. 2017 May;197(5):1302-8. PMID: 27871927
33. Wallis, MC, Davies, EA, Thalib, L, Griffiths, S. Pelvic static magnetic stimulation to control urinary incontinence in older women: a randomized controlled trial. *Clinical medicine & research*. 2012 Feb;10(1):7-14. PMID: 21817123
34. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. *Obstetrics and gynecology*. 2015 Nov;126(5):e66-81. PMID: 26488524
35. American Urological Association (AUA). Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline. 2014. [cited 10/25/2017]; Available from: [http://www.auanet.org/guidelines/overactive-bladder-\(oab\)-\(aua/sufu-guideline-2012-amended-2014\)](http://www.auanet.org/guidelines/overactive-bladder-(oab)-(aua/sufu-guideline-2012-amended-2014))
36. BlueCross BlueShield Association Medical Policy Reference Manual "Pelvic Floor Stimulation as a Treatment of Urinary Incontinence." Policy No. 1.01.17

## CODES

**NOTE:** There is no specific code for the administration of pelvic floor stimulation.

Codes	Number	Description
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	Non-implanted pelvic floor electrical stimulator, complete system

**Date of Origin:** January 1996