Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

Effective: December 1, 2023

Next Review: October 2024
Last Review: October 2023

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 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. Periurethral Transperineal Adjustable Balloon Continence Device, Medicine, Policy No. 176
2. Sacral Nerve Neuromodulation (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 ReviewsAlouni (2022) evaluated the effectiveness of pelvic floor muscle training (PFMT) with or without biofeedback or electrostimulation in reducing urinary incontinence and pelvic floor muscle contraction in non-pregnant women with urinary incontinence.[1] Fifteen RCTs were retrieved using the strict inclusion and exclusion criteria, assessing 2441 non-pregnant women with urinary incontinence. Of the 15 studies, seven were low risk, five were medium risk, and three were high-risk studies. Of the 2441 patients, 970 were in PFMT, 69 were in extracorporeal magnetic innervation (ExMi) or with PFMT + BF, 30 were in electrostimulation (ES), 21 were in whole body vibration training (WBVT), 23 were in pelvic floor muscle + abdominal muscle therapy (PFM + AMT), 326 were in PFMT + biofeedback, 93 were in vaginal cones (VC), 362 were in PFMT + education, 318 were in education, and 229 were in control groups. PFMT alone or with bio-feedback or electrostimulation was effective in reducing urinary incontinence and improving pelvic floor muscle contraction. For the systematic review and meta-analysis by Zhu (2022) eligible randomized controlled trials on postpartum lower urinary tract symptoms comparing PFMT plus biofeedback, ES, or both with PFMT alone were included.[2] The authors also concluded that PFMT plus ES with or without biofeedback exhibited better efficacy and safety for early postpartum lower urinary tract symptoms than PFMT alone.

Stania (2022) published a systematic review and meta-analysis to determine the therapeutic efficacy of intravaginal electrical stimulation (ES) in women with stress urinary incontinence (SUI).[3] RCTs were searched from PubMed, Embase, EBSCOHost and Ovid. Of the 686 records identified, a total of 10 articles met the inclusion criteria. A meta-analysis revealed significant differences between the ES and no active treatment groups in the pooled objective cure rates (RR: 4.20; 95% CI 1.70 to 10.40; p = 0.001; I2 = 0%) and subjective cure or improvement rates (RR: 4.96; 95%: 1.01 to 24.37; p = 0.04; I2 = 0%). No significant differences were found in the pooled number of incontinence episodes per 24 h (MD: 0.16; 95% CI 0.68 to 0.37; p = 0.56; I2 = 0%), the pooled Incontinence Quality of Life Questionnaire scores (MD: 1.84; 95% CI 2.11 to 5.80; p = 0.36; I2 = 0%) or the pooled number of adverse effects (RR: 0.69; 95% CI 0.38 to 1.27; p = 0.23; I2 = 0%) between the ES and other conservative treatment groups. The authors concluded that there is insufficient evidence for or against the use of intravaginal ES therapy for women with SUI.

Leonardo (2022) published a systematic review and meta-analysis of eight RCTs (N=562) which evaluated the comparative effectiveness of biofeedback-assisted pelvic floor muscle training (PFMT) versus PFS versus a control group (PFMT alone, bladder training, or lifestyle recommendations only) in women with overactive bladder.[4] Outcomes assessed included quality of life, number of episodes of incontinence, and number of patients who improved or were cured. The PFS group exhibited significant differences in quality of life (mean difference, 7.41; 95% CI 7.90 to 12.92; p=0.008), episodes of incontinence (mean difference, -1.33; 95% CI -2.50 to -0.17; p=0.02), and the number of patients who improved or were cured (risk ratio, 1.46; 95% CI 1.14 to 1.87; p=0.003) compared to the control group. The biofeedback-assisted PFMT group did not have significant differences in any of these outcomes compared to the control group. Limitations of the study include high heterogeneity for some analyses and

differences in the qualitative and quantitative assessments utilized in the included RCTs which limits the direct comparability among the studies.

A 2017 Cochrane systematic review evaluated the effect of PFS on self-reported incontinence.[5] The review found no difference between PFS and pelvic floor muscle training (PFMT) in likelihood of cure of stress incontinence at six months based on the results of four RCTs (n=143; RR 0.51, 95% CI 0.15 to 1.63). There was also no difference between groups in adverse event rates based on an imprecise estimate (RR 5.00, 95% CI 0.25 to 99). Quality of life was not reported. The same review included studies comparing PFS + PFMT versus PFMT alone, finding no difference between groups in incontinence rates based on three trials (n=99; RR 0.76, 95% CI 0.38 to 1.52). The review found a small benefit of PFS + PFMT on incontinence-related quality of life when compared with PFMT alone (SMD -0.77, 95% CI -1.11 to -0.42). The review deemed the evidence for PFS alone or in combination with PFMT versus PFMT inconclusive for incontinence and quality of life outcomes.

In 2016, Moroni published a systematic review of conservative treatment of stress urinary incontinence.[6] 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.[7] 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 Trials (RCTs)

RCTs published since the Cochrane systematic review are summarized here.

Yildiz (2022) evaluated the effect of intravaginal electrical stimulation (IVES) therapies with

different treatment frequencies (two or five days in a week) added to bladder training (BT) on incontinence-related QoL and clinical parameters in women with refractory idiopathic overactive bladder (OAB).[8] Fifty-two women with refractory idiopathic OAB were randomized into two groups as follows: Group 1 (n=26) received BT and IVES, two times in a week, for 10 weeks and Group 2 (n=26) received BT and IVES five times in a week, for four weeks. IVES was performed 20 minutes in a day, a total of 20 sessions for both groups. There were no statistically significant differences in all parameters between the two groups at the end of the treatment. The authors concluded that the application of IVES twice a week or five times a week added to BT were both effective on incontinence-related QoL and clinical parameters in women with refractory idiopathic OAB.

Yildiz (2021) evaluated the efficacy of IVES added to bladder training (BT) on idiopathic overactive bladder in a randomized controlled trial.[9] Changes in incontinence-related quality of life (QoL) and clinical parameters were evaluated in 62 women with idiopathic OAB randomized to receive BT or BT+IVES. For women receiving IVES, this treatment was delivered in 24 sessions that were 23 minutes in length over eight weeks. The outcomes measured were incontinence severity (24-hour pad test), pelvic floor muscles (strength perineometer), three-day voiding diary (frequency of voiding, nocturia, incontinence episodes and number of pads), symptom severity (OAB-V8), incontinence-related QoL (IIQ-7), treatment success (positive response rate), cure/improvement rate and treatment satisfaction (Likert scale). Incontinence severity, frequency of voiding, nocturia, incontinence episodes, number of pads, symptom severity, and QoL were significantly improved in the stimulation group compared to the BT-alone group at the end of treatment ($p<0.05$). In addition, treatment satisfaction, cure/improvement, and positive response rates were significantly higher in the stimulation group compared to the BT-alone group at the end of treatment ($p<0.05$).

Antonio (2022) assessed the effect of IVES in women who are unable to contract the pelvic floor muscles voluntarily.[10] In this RCT, 64 women received weekly 20-minute sessions of intravaginal electrical stimulation with instructions to attempt pelvic floor muscle contractions during the bursts of electrical stimulation in the final 10 minutes of each session for eight weeks. Sixty-one participants provided outcome data. After the intervention, the ability to contract the pelvic floor muscles was acquired by 36% of the experimental group and 12% of the control group (absolute risk difference 0.24; 95% CI 0.02 to 0.43). The authors concluded that IVES eight weeks of IVES reduced the overall severity and impact of urinary incontinence on QoL.

Oldham (2021) reported the results of a community-based open-label randomized trial that compared treatment as usual to a disposable home vaginal electro-stimulation device in addition to treatment as usual.[11] Treatment as usual consisted of each General Medical Practitioner's (GP) standard practice. While that should have consisted of various practices based on National Institute for Health and Care Excellence (NICE), in practice, only 21 to 27% received pelvic floor exercise advice from the GP or a nurse and the remainder received little or no intervention, which is not in line with NICE guidelines. The stimulation group was prescribed a 12-week (30-min every other day) course of electrical stimulation. The trial was terminated early due to COVID-19, which resulted in recruitment of 86 women of the intended 132 per group. The primary outcome was quality of life, as measured by the International Consultation on Incontinence Questionnaire—Urinary Incontinence (ICIQ-UI-SF). The difference in groups for this measure at the 12-week follow-up was statistically significant, with superior results in the stimulation group ($p=0.034$). Differences between groups on the Patient Global Impression of Severity (PGI-S) were also statistically significant at six weeks ($p=0.001$)

and 12 weeks (p<0.001), again favoring stimulation. Results for sexual health were mixed, depending on the tool used for measurement.

Bacchi Ambrosano Giarreta (2020) published a randomized controlled trial of the addition of vaginal electrical stimulation to transcutaneous tibial nerve electrical stimulation (TTNS) for women with overactive bladder.[12] A total of 106 women were randomized to the TTNS group or the TTNS plus vaginal stimulation group. Outcomes reported were three-day voiding diary, pelvic floor muscle strength (Ortiz Scale), King's Health Questionnaire, and Overactive Bladder Questionnaire assessed after vs. before treatment. A statistically significant but not clinically relevant reduction in urinary frequency (1.5 micturitions) was reported in the combination treatment group.

Firinci (2020) reported results of a randomized controlled trial comparing single and combined use of biofeedback and electrical stimulation added to bladder training in women with idiopathic overactive bladder.[13] The 17 to 18 patients per group received bladder training alone, biofeedback plus bladder training, bladder training plus electrical stimulation, or all three treatments. The two groups that included electrical stimulation had statistically significant improvements in severity of incontinence, frequency of voiding, incontinence episodes, and treatment satisfaction compared to the other groups. For nocturia, the group that received all three treatments had statistically significant improvements over all of the other groups, and the group with bladder training alone had the poorest outcomes. Differences in cure/improvement and positive response rates between the groups that received electrical stimulation and those that did not were statistically significant, with better outcomes reported in those receiving electrical stimulation.

Hwang (2020) randomized 34 stress urinary incontinence patients to the surface electrical stimulation group or control group.[14] Surface electrical stimulation was delivered in a seated position. Measurements of pelvic floor muscle functions (strength, power, and endurance) as measured via perineometry, the score on the urogenital distress inventory-6 (UDI-6), and the ultra-short perineal pad test result were taken before treatment and after eight weeks of treatment. Statistically significant differences between groups and pre- vs. post-treatment were reported for all measures, with better outcomes reported for stimulation.

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.[15] 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 to -0.5]) and daily episodes of urinary incontinence (-0.4 [95% CI -0.8 to -0.1]).

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

Sciarra (2021) conducted meta-analyses comparing the effect of PFS with pelvic floor muscle training and biofeedback on urinary incontinence in men following radical prostatectomy.[16] The review included five RCTs of PFS, the most recent of which was published in 2018. PFS devices, frequency and duration varied among the trials. At three months, the effect size for continence recovery (based on pad-free event rate) was 0.57 (95% CI 0.46 to 0.69) for PFS, 0.40 (95% CI 0.30 to 0.49) for pelvic floor muscle training and 0.54 (95% CI 0.32 to 0.75) for biofeedback (p=0.01 for both PFS and biofeedback versus pelvic floor muscle training). At six and 12 months, PFS effect sizes were 0.78 (95% CI 0.59 to 0.98) and 0.82 (95% CI 0.65 to 0.99) and there was no longer a statistically significant difference between any treatment group and rate of continence recovery.

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.[17] 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=3,503, 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.[18] 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.[19] Three RCTs[20-22] 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.

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 simulation 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.[23] One RCT was sham-controlled[24], one compared electrical stimulation with levatorplasty[25], and two used electrical stimulation as an adjunct treatment[26, 27]. 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.[28] 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[29, 30] 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).[31] 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[7] identified five RCTs that compared active to sham magnetic stimulation in women with UI[32], stress UI[33, 34], mixed[34] or predominant urgency UI[35]. 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[32] reported increased continence rates. Pooled analysis demonstrated no significant increase in rate of continence between active and sham stimulation. For improvement in UI, two[32, 33] of the three[32, 33, 35] 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[36] of the two[34, 36] 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 [37] 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).[38] Patients were randomized to receive active or sham PMS twice per week, for eight 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.[39] 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.[40] 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.[41] 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.[19] 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.”[42] 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 2019 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.[43] 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.

AMERICAN COLLEGE OF GASTROENTEROLOGY

In 2021, the American College of Gastroenterology issued guidelines on the management of benign anorectal disorders.[44] In the section on fecal incontinence, pelvic floor stimulation (PFS) is not mentioned as a treatment option.

AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS

In 2023, the American Society of Colon and Rectal Surgeons updated an evidence-based guideline using GRADE methodology on treatment of fecal incontinence.[45] Dietary interventions and medical management are considered first-line treatments; pelvic floor stimulation was not included in the recommendations.

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.

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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*