PHP_1.01.17	Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence		
Original Policy Date:	December 1, 2025	**Effective Date:**	June 1, 2026
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 20

State Guidelines

Applicable Medi-Cal guidelines as of the publication of this policy (this guideline supersedes the criteria in the Policy Statement section below):

I. Department of Managed Health Care (DMHC) All Plan Letter (APL) Guideline:
- N/A

II. Department of Health Care Services (DHCS) Provider Manual Guideline:
- TAR and Non-Standard Benefits List: Codes 90000 thru 99999 (tar and non cd9)
- TAR and Non-Standard Benefits List: Codes E0000 thru E9999 (tar and non cde)
- TAR and Non-Standard Benefits List: Codes G0000 thru G9999 (tar and non cdg)

The codes listed on the policy are included in the above Provider Manuals; however, there are no specific clinical guidelines.

III. Department of Health Care Services (DHCS) All Plan Letter (APL) Guideline:
- N/A

NOTE: Refer to Appendix A to see the state guidelines/policy statement changes (if any) from the previous version.

Policy Statement

Any criteria that are not specifically addressed in the above Provider Manuals, please refer to the criteria below.

I. Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) is considered **investigational** as a treatment for **either** of the following:
   A. Urinary incontinence
   B. Fecal incontinence

Policy Guidelines

Coding
See the Codes table for details.

Description

Pelvic floor stimulation is proposed as a nonsurgical treatment option for women and men with urinary or fecal incontinence. This approach involves either electrical stimulation of pelvic floor musculature or extracorporeal pulsed magnetic stimulation.

Summary of Evidence

For individuals who have urinary incontinence who receive electrical pelvic floor stimulation (PFS), the evidence includes systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Findings from systematic reviews have not found that electrical PFS used to treat urinary incontinence in women consistently improves the net health outcome compared with placebo or other conservative treatments. Moreover, meta-analyses of RCTs have not found a significant benefit of electrical PFS in men with postprostatectomy incontinence compared with a control intervention. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fecal incontinence who receive electrical PFS, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Among the RCTs that have evaluated electrical PFS as a treatment for fecal incontinence, only 1 trial was sham-controlled, and it did not find that electrical stimulation improved the net health outcome. Systematic reviews of RCTs have not found that electrical stimulation is superior to control interventions for treating fecal incontinence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have urinary incontinence who receive magnetic PFS, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review of RCTs on magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the following factors: a low number of trials with short-term follow-up, methodologic limitations, as well as heterogeneity in patient populations, interventions, and outcomes reported. One RCT evaluating magnetic stimulation for treating men with postprostatectomy urinary incontinence reported short-term results favoring magnetic PFS; however, the trial was small and lacked a sham comparator. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fecal incontinence who receive magnetic PFS, no relevant evidence was identified. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

Related Policies

- N/A

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

Regulatory Status

Several electrical stimulators have been cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) process, such as nonimplanted electrical stimulators for treating urinary incontinence and predicate devices which are also used to treat urinary incontinence.

FDA product code: KPI.

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

Rationale

Background

Pelvic Floor Stimulation

Pelvic floor stimulation (PFS) involves electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation or, more recently, extracorporeal electromagnetic (also called magnetic) pulses. Stimulation of the pudendal nerve to activate the pelvic floor musculature may improve urethral closure. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. Methods of electrical PFS have varied in location (e.g., vaginal, rectal), stimulus frequency, stimulus intensity or amplitude, pulse duration, pulse to rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, and overall time period for device use between clinical and home settings. Variations in the amplitude and frequency of the electrical pulse are used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the etiology of the incontinence (i.e., either detrusor instability, stress incontinence, or a mixed pattern). Magnetic PFS does not require an internal electrode; instead, patients sit fully clothed on a specialized chair with an embedded magnet.

Patients receiving electrical PFS may undergo treatment in a physician's office or physical therapy facility, or patients may undergo initial training in a physician's office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS may be administered in the physician's office.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Electrical Pelvic Floor Stimulation for Urinary Incontinence

Clinical Context and Therapy Purpose

The purpose of pelvic floor stimulation (PFS) in individuals who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with urinary incontinence. Types of urinary incontinence include stress incontinence, urgency incontinence, and mixed (both stress and urgency).

Urinary incontinence is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence.[1] Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history.

Urinary incontinence is less common in men, with estimates ranging from 11% to 16%[2] in men greater than 65 years. Factors that increase a man's risk include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Interventions

The therapy being considered is electrical PFS for urinary incontinence. In an electrical PFS procedure, a probe delivers electrical pulses to stimulate the pudendal nerve, which activates the pelvic floor musculature. Activation of this musculature is believed to improve urethral closure.

Comparators

The following therapies are currently being used to make decisions about urinary incontinence: magnetic PFS or neuromodulation, behavioral therapies (e.g., monitoring fluid intake, bladder, and pelvic floor muscle training, diet), and medications.

Outcomes

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Short-term results can be measured at 6 months.[3] Longer-term follow-up may be necessary to determine if treatment has durable effects.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Urinary Incontinence in Women

Systematic Reviews
A Technology Evaluation Center (TEC) Assessment (2000) concluded there was insufficient evidence that electrical PFS improved health outcomes compared with placebo or other behavioral therapies in women with stress, urge, or mixed incontinence[4]

Subsequently, several systematic reviews of the literature with pooled study findings have been published.

Naidu et al (2025) published a systematic review of RCTs (N=32 trials) evaluating the use of intravaginal electrical stimulation for the treatment of urinary incontinence in women.[5] No meta-analysis was performed due to heterogeneity in protocols and trial quality. A narrative synthesis of outcomes showed that intravaginal electrical stimulation was associated with favorable within-group improvements in incontinence symptoms, but its superiority over active comparators (e.g., pelvic floor muscle training [PFMT], biofeedback) was inconsistent. Of 8 trials reporting pad use, 6 found significant reductions within intravaginal electrical stimulation groups. A pooled summary of 15 trials on pad weight found 10 reporting significant reductions post-intravaginal electrical stimulation, though differences between intravaginal electrical stimulation and active comparators were generally non-significant. Nineteen trials assessed pelvic floor muscle strength; 11 demonstrated significant within-group improvements, though PFMT often showed greater effects than intravaginal electrical stimulation. Across 27 trials assessing QOL, 15 found significant improvements in the intravaginal electrical stimulation groups, although between-group comparisons varied. Adherence to intravaginal electrical stimulation was moderate to high (61 to 100%), and adverse events were infrequent and mild (e.g., irritation, discomfort).

Leonardo et al (2022) published a systematic review and meta-analysis of 8 RCTs (N=562) which evaluated the comparative effectiveness of biofeedback-assisted PFMT versus PFS versus a control group (PFMT alone, bladder training, or lifestyle recommendations only) in women with overactive bladder.[6] 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% confidence interval [CI], 7.90 to 12.92; p=.008), episodes of incontinence (mean difference, -1.33; 95% CI, -2.50 to -0.17; p=.02), and the number of patients who improved or were cured (risk ratio, 1.46; 95% CI, 1.14 to 1.87; p=.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 review evaluated the effect of PFS on self-reported incontinence.[7] The review found no difference between PFS and PFMT in the likelihood of cure of stress incontinence at 6 months based on the results of 4 RCTs (N=143; relative risk [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 3 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 (standard mean difference, -

0.77; 95% CI, -1.11 to -0.42). The review deemed the evidence for PFS alone or in combination with PFMT versus PFMT alone inconclusive for incontinence and quality of life outcomes.

An Agency for Healthcare Research and Quality comparative effectiveness review prepared by Shamliyan et al (2012) identified 9 RCTs evaluating electrical intravaginal stimulation in women with urgency, stress, or mixed incontinence.[8] Eight of the 9 studies were published in 2000 or earlier; nearly all used a sham treatment as the control. A pooled analysis of continence rates in 8 RCTs comparing electrical PFS with no active treatment yielded an RR of 2.86 (95% CI, 1.57 to 5.23). A pooled analysis of the reduction in incontinence symptoms yielded an RR of 2.01 (95% CI, 1.28 to 3.15). Reviewers concluded that a high level of evidence suggested electrical PFS is associated with increased continence rates, and that such stimulation improved urinary incontinence.

Moroni et al (2016) published a systematic review of conservative treatment for stress urinary incontinence.[9] Five trials (N=221 women) were identified comparing intravaginal electrical PFS with control. There were insufficient data on cure rates (eg, continence rates). A pooled analysis of 4 studies reporting urine quantity with a pad weight test found a significantly greater reduction in pad weight in the treatment versus control groups (mean difference, -9.15; 95% CI, -17.22 to -1.08). A pooled analysis of 2 studies found significantly greater improvement in the incontinence-specific quality of life in the electrical PFS group than in the control group (mean difference, -1.44; 95% CI, -1.94 to -0.95). Three studies were included in a pooled analysis of a number of incontinence episodes; the findings were not reported. Reviewers stated that, among all conservative treatments assessed, evidence was strongest in support of PFS, with or without biofeedback, for treatment of stress urinary incontinence.

Men With Postprostatectomy Urinary Incontinence

Systematic Reviews

Tang et al (2025) conducted a systematic review and meta-analysis comparing the effectiveness of electrical stimulation combined with pelvic floor muscle exercises (PFME) versus PFME alone for treating male urinary incontinence after radical prostatectomy.[10] The review included 10 RCTs published between 1999 and 2024, with treatment durations ranging from 2 to 12 months. Electrical stimulation methods and devices varied across studies, including perineal, transanal, and combined approaches. Outcomes assessed included 24-hour pad test, International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), incontinence control rate, and QOL. In the short term (≤3 months), electrical stimulation significantly improved incontinence symptoms, with a marked reduction in ICIQ-SF scores (mean difference, -3.50; 95% CI, -5.11 to -1.89; p <.0001) and a doubling of continence control rates (risk ratio, 2.01; 95% CI, 1.17 to 3.44; p =.01), although no benefit was observed for objective leakage volume or quality of life. In contrast, long-term treatment (≥6 months) with electrical stimulation significantly reduced urinary leakage based on the 24-hour pad test (mean difference, -21.64; 95% CI, -40.03 to -3.25; p =.02), but showed no significant improvement in ICIQ-SF scores or continence rates. Analysis of QOL outcomes found no significant difference between the electrical stimulation group and the control group.

Sciarra et al (2021) conducted meta-analyses comparing the effect of PFS with PFMT and biofeedback on urinary incontinence in men following radical prostatectomy.[11] The review included 5 RCTs of PFS, the most recent of which was published in 2018. PFS devices, frequency, and duration varied among the trials. At 3 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 PFMT, and 0.54 (95% CI, 0.32 to 0.75) for biofeedback (p=.01 for both PFS and biofeedback vs. PFMT). At 6 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), respectively, and there was no longer a statistically significant difference between any treatment group and rate of continence recovery.

A Cochrane review by Berghmans et al (2013) identified 6 RCTs on electrical PFS with nonimplanted electrodes for postprostatectomy urinary incontinence in men.[12] The trials varied by intervention used,

study protocols, study populations, and outcome measures. In a pooled analysis of 4 RCTs comparing the combination of electrical stimulation and pelvic floor muscle exercises with pelvic floor muscle exercises alone, there was no statistically significant difference between groups in the proportion of men with urinary incontinence at 3 months (RR, 0.93; 95% CI, 0.82 to 1.06). Findings from studies evaluating electrical PFS alone were not pooled. A 2023 Cochrane review on conservative interventions for managing urinary incontinence after prostate surgery found no studies on electrical or magnetic stimulation compared with no treatment, sham, or verbal/written instructions that reported on key outcomes.[13]

Zhu et al (2012) conducted a meta-analysis and reported similar findings for electrical PFS to treat postprostatectomy urinary incontinence.[14] Reviewers identified 4 RCTs (N=210 men) that provided sufficient data on clinical outcomes. A pooled analysis of data from 3 trials did not find a statistically significant benefit of electrical PFS on continence levels compared with controls within 3 months of prostatectomy (RR, 1.21; 95% CI, 0.96 to 1.54). Similarly, a pooled analysis of data from all 4 trials did not show a statistically significant benefit of electrical PFS on continence levels 6 to 12 months after prostatectomy (RR, 1.03; 95% CI, 0.88 to 1.20).

Randomized Controlled Trials

No additional RCTs were identified relevant to this review.

Section Summary: Electrical Pelvic Floor Stimulation for Urinary Incontinence

A majority of RCTs on electrical PFS for treatment of women with urinary incontinence have been published before 2001. Meta-analyses of RCTs have had inconsistent findings on the impact of electrical intravaginal stimulation on urinary incontinence in women compared with sham treatment.

For the treatment of urinary incontinence in men, pooled analyses from 4 systematic reviews found inconsistent evidence on the effect of PFS on continence at 3 months (2 found significant benefit and 2 did not), and found no clear benefit of PFS at 6- and 12-month follow-up.

Electrical Pelvic Floor Stimulation for Fecal Incontinence

Clinical Context and Therapy Purpose

The purpose of PFS in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with fecal incontinence. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence. Risk factors for fecal incontinence are similar in men and women: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes.

Interventions

The therapy being considered is electrical PFS for fecal incontinence.

Comparators

The following therapies are currently being used to make decisions about fecal incontinence: nonsurgical treatment options and behavioral therapies. Nonsurgical treatment options for incontinence may include pharmacologic therapy, bowel training exercises, and magnetic stimulation. Behavioral therapies include pelvic floor muscle training and diet.

Outcomes
The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Electrical PFS therapy generally continues for 6 to 8 weeks.[15,16]

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
A systematic review by Vonthein et al (2013) searched for studies on the impact of biofeedback and/or electrical PFS for treating fecal incontinence in adults.[17] They identified 13 RCTs that used 1 or both of these treatments and reported health outcomes (eg, remission or response rates using validated scales). A pooled analysis of trial results did not find statistically significant differences in rates of remission when comparing electrical PFS with a control intervention (RR, 0.47; 95% CI, 0.13 to 1.72). A pooled analysis of studies comparing electrical PFS plus biofeedback with electrical PFS 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 PFS. Additionally, the confidence interval was very wide, indicating an imprecise estimate of the treatment effect. The Vonthein et al (2013) review included only 2 RCTs on electrical PFS[18,19] that were published after a Cochrane review (below). These 2 trials included the combination of amplitude-modulated medium-frequency stimulation and biofeedback. Electrical PFS was not evaluated in the absence of biofeedback.

A Cochrane review by Hosker et al (2007) identified 4 RCTs evaluating electrical stimulation as a treatment of fecal incontinence in adults.[20] One trial was sham-controlled, another compared electrical PFS with levatorplasty, and 2 used electrical PFS as an adjunct treatment. Reviewers did not pool study findings; they concluded that there is insufficient evidence to draw conclusions on the efficacy of electrical PFS for treating fecal incontinence.

Randomized Controlled Trials
An RCT by Cohen-Zubary et al (2015) allocated 42 women with fecal incontinence to 6 weeks of electrical stimulation (n=22) or biofeedback training (n=20).[15] Biofeedback sessions were conducted in-clinic and electrical PFS sessions at home following an initial training in-clinic. Thirty-six (86%) women completed the trial and were included in the analysis; the analysis was not intention-to-treat. The trial's primary endpoints were improvements in frequency of fecal, urine, and gas incontinence, assessed using visual analog scale scores. There were no statistically significant differences between groups for the primary outcomes. The mean visual analog scale score (standard deviation [SD]) for solid stool incontinence at baseline in the stimulation group was 2.9 (2.8), which decreased to 0.9 (0.9) at follow-up. In the biofeedback group, the baseline visual analog scale score was 1.1 (2.1) and 0.3 (0.5) at follow-up. The between-group difference for this outcome was not statistically significant. For within-group changes, the electrical stimulation group improved significantly on solid stool incontinence, but not on liquid stool or gas incontinence, and the biofeedback group did not improve significantly on any of the fecal incontinence outcomes.

Norton et al (2006) in the U.K. published a sham-controlled randomized trial that included 90 adults with fecal incontinence.[16] Patients used a home electric PFS device for 8 weeks. Patients allocated to

active treatment had the stimulation set at 35 Hz, with a 0.5-second ramped pulse. The sham stimulator looked identical but stimulation was set at 1 Hz below the level tested for therapeutic effect. Patients were blinded to the treatment group; although nurses who trained patients on device use were not. The primary outcome was patient self-report of efficacy, using a rating scale ranging from -5 to +5 to indicate symptom change. Seventy (78%) of the 90 patients completed the trial. In an intention-to-treat analysis (assigning patients who dropped out a value of 0), there was no statistically significant difference between groups in patient ratings of symptom change. On a scale of -5 to +5, there was a median rating of 0 in each group (p=.92). In a completer analysis, the median change in symptoms was 2 in the active treatment group and 1 in the sham group (p=.74). Groups did not differ significantly on other secondary outcomes such as the frequency of urge or passive incontinence after treatment.

Section Summary: Electrical Pelvic Floor Stimulation for Fecal Incontinence

Several RCTs have evaluated electrical stimulation for treating fecal incontinence. Only 1 was sham-controlled, and it did not find that active stimulation produced better results than sham stimulation. Systematic reviews of RCTs have not found that electrical stimulation is superior to control interventions for treating fecal incontinence.

Magnetic Pelvic Floor Stimulation for Urinary Incontinence

Clinical Context and Therapy Purpose

The purpose of magnetic PFS in individuals who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with urinary incontinence. Types of urinary incontinence include stress incontinence, urgency incontinence, and mixed (both stress and urgency). Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history. Urinary incontinence is less common in men, with estimates ranging from 11% to 34% in men greater than 65 years. Factors that increase a man's risk include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Interventions

The therapy being considered is magnetic PFS for urinary incontinence. The mechanism of action of a magnetic PFS procedure is similar to the electrical procedure, though using magnetic pulses to activate the pelvic floor musculature. The magnetic pulses are delivered without a probe, with patients sitting fully clothed in a specialized chair with an embedded magnet.

Comparators

The following therapies are currently being used to make decisions about urinary incontinence: electrical PFS and behavioral therapies (e.g., monitoring fluid intake, pelvic floor muscle training, diet), and medications.

Outcomes

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Treatment is for approximately 8 weeks, and follow-up is generally up to 6 months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Women with Urinary Incontinence

Systematic Reviews
A systematic review of RCTs on magnetic stimulation for the treatment of urinary incontinence was published by Lim et al (2015).[21] Reviewers identified 8 blinded, sham-controlled trials (N=484). Treatment protocols (e.g., frequency, duration of magnetic PFS) varied among trials. The primary outcome was cure rate; only 1 trial reported this outcome, so data were not pooled. A meta-analysis of 3 studies reporting improvements in the continence rates found significantly greater improvement in the treatment group than in the 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 not pooled for other outcomes. Reviewers noted that the evidence was limited by low-quality trials with short-term follow-up.

Randomized Controlled Trials
Lim et al (2017) randomized 120 women with stress urinary incontinence to treatment with magnetic PFS (QRS®-1010 PelviCenter) or sham treatment.[22] Patients received 2 sessions per week for 8 weeks (16 sessions). Patients who were unsatisfied after 2 months were allowed 16 additional active sessions in an open-label phase. All participating study centers were located in Malaysia. The primary endpoint of response was defined as a 5-point reduction on the International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form (ICIQ-UI SF). A total of 45 (75.0%) patients responded at 2 months in the active treatment group compared with 13 (21.7%) patients in the sham group (RR, 3.46; 95% CI, 2.09 to 5.72; p<.001). At long-term follow-up (14 months), the patients who received 16 or more active sessions had improved response rates than those who received none (response rates of 68.3% to 75.0% vs. 21.1%). The study is limited by the small sample size and the limited demographic heterogeneity.

Men With Postprostatectomy Urinary Incontinence
Systematic Review
A 2023 Cochrane review on conservative interventions for managing urinary incontinence after prostate surgery found no studies on electrical or magnetic stimulation compared with no treatment, sham, or verbal/written instructions that reported on key outcomes.[13]

Randomized Controlled Trial
Unal et al (2025) evaluated the efficacy of magnetic stimulation in men with urinary incontinence following radical prostatectomy.[23] Forty patients were assigned to receive either active magnetic stimulation (n=20) or sham treatment (n=20) using the Novamag NT60 therapy chair, administered twice weekly for 8 weeks (16 sessions). Primary outcomes included improvement in incontinence severity, quality of life, sexual function, depression, and anxiety. At 8 weeks, the active treatment group showed significant improvements in all measured outcomes except some subdomains of sexual function (erectile function, sexual desire, intercourse satisfaction, and overall satisfaction) and depression. In contrast, the sham group showed limited improvement, primarily in incontinence severity and bladder diary metrics. Between-group comparisons revealed greater improvements in the magnetic stimulation group in terms of incontinence severity, nocturia, incontinence episodes, QOL, orgasmic function, and anxiety (p<0.05). Improvement rates (75.0% vs. 26.3%), continence rates (45.0% vs. 15.8%), and treatment satisfaction (effect size d=1.23) were also significantly higher with magnetic stimulation.

Section Summary: Magnetic Pelvic Floor Stimulation for Urinary Incontinence

A systematic review of RCTs evaluating the use of magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the small number of trials with short-term follow-up, methodologic limitations, and heterogeneity in terms of patient populations, interventions, and outcome reporting.

A 2023 systematic review was unable to identify studies on magnetic PFS evaluating outcomes of interest in men with urinary incontinence. One RCT found that magnetic stimulation significantly improved urinary incontinence severity, quality of life, anxiety, and several sexual function parameters in men post-prostatectomy compared to sham treatment, with notably higher improvement and continence rates and treatment satisfaction.

Magnetic Pelvic Floor Stimulation for Fecal Incontinence

Clinical Context and Therapy Purpose

The purpose of PFS in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with fecal incontinence. Risk factors for fecal incontinence are similar in men and women: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes. For women, current and past use of hormone therapy is an added risk factor. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence.

Interventions

The therapy being considered is magnetic PFS for fecal incontinence. The mechanism of action of a magnetic PFS procedure is similar to the electrical procedure, though using magnetic pulses to activate the pelvic floor musculature. The magnetic pulses are delivered without a probe, with patients sitting fully clothed in a specialized chair with an embedded magnet.

Comparators

The following therapies are currently being used to make decisions about fecal incontinence: nonsurgical treatment options and behavioral therapies. Nonsurgical treatment options for incontinence may include pharmacologic therapy, bowel training exercises, and electrical stimulation. Behavioral therapies include pelvic floor muscle training and diet.

Outcomes

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Treatment is for approximately 8 weeks, and follow-up is generally up to 6 months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
No studies were identified that evaluated magnetic PFS as a treatment for fecal incontinence.

Section Summary: Magnetic PFS for Fecal Incontinence
Current evidence is insufficient to draw conclusions about the efficacy of magnetic PFS to treat fecal incontinence.

Supplemental Information
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology
In 2021, the American College of Gastroenterology issued guidelines on the management of benign anorectal disorders.[24] 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.[25] Dietary interventions and medical management are considered first-line treatments; PFS was not included in the recommendations.

American Urological Association et al
In 2024, the American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) updated guidelines on the diagnosis and management of overactive bladder.[26] Electromagnetic therapy is included as an example of non-invasive therapy. The recommendation states, "Clinicians may offer select non-invasive therapies to all patients with OAB." However, the guidelines also state, "While safety profiles are excellent across modalities, with few adverse effects and a high risk-benefit ratio, all non-invasive therapies do not have equivalent efficacy, and the evidence base is highly variable. Most non-invasive therapies require long-term patient compliance to maintain a durable effect, and patients should be counselled as such before embarking on a course of a potentially lifelong therapy." There is no additional information specific to PFS in the guidelines.

Joint guidelines issued in 2019 by the AUA and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) on management of post-prostatectomy urinary incontinence do not specifically address electrical or magnetic PFS as treatment options. Pelvic floor muscle training/exercise is recommended as first-line treatment for post-prostatectomy incontinence.[27] These guidelines were updated and amended in 2024, however they still do not specifically address electrical or magnetic PFS as treatment options.[28]

National Institute for Health and Care Excellence
In 2019, the NICE issued guidance on the management of urinary incontinence in women.[29] The NICE stated that electrical stimulation, alone or as an adjunct to pelvic floor muscle training, should not be routinely used to treat women with overactive bladder. The NICE guidance further stated: "electrical

stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy." Magnetic PFS is not mentioned.

In 2007, the NICE issued guidance on the management of fecal incontinence in adults.[30] This guidance was last reviewed by NICE in 2018. The document stated that the evidence on electrical stimulation for treatment of fecal incontinence was inconclusive. The NICE recommended that patients who continue to have episodes of fecal incontinence after initial treatment be considered for specialized management, which may include electrical PFS. Magnetic PFS is not mentioned.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The national coverage determination for Non-Implantable Pelvic Floor Electrical Stimulator (230.8) stated: "Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training."[31] The effective date was June 19, 2006.

The document did not mention fecal incontinence.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05952258	Magnetic Stimulation as a Treatment for Stress urinary Incontinence	158	Jul 2026
NCT05680168	Efficacy of Extracorporeal Magnetic Stimulation, Pelvic Floor Muscle Exercise, and Combination of Both in Management of Post Radical Prostatectomy Urinary Incontinence: A Randomized Controlled Trial	60	Dec 2029

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	E0715	Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
	E0716	Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
	E0740	Non-implanted pelvic floor electrical stimulator, complete system
	G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/01/2025	New policy.
05/01/2026	Administrative update. State Guidelines section updated.
06/01/2026	Administrative update. Definitions of Decision Determinations section updated.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status

Below is an excerpt of the language taken from California Children's Services Numbered Letter 05-1020.*

*Department of Healthcare Services Numbered Letter 05-1020. Accessed April 21, 2026, from https://www.dhcs.ca.gov/services/ccs/Documents/CCS-NL-05-1020-Experimental-and-Investigational-Services.pdf

Policy

A. The California Children's Services (CCS) Program and the Genetically Handicapped Persons Program (GHPP) will not provide coverage for experimental services unless specifically authorized by law.
B. The CCS Program and GHPP may provide coverage for an investigational service if:
    1. It is approved by the FDA under any Investigational New Drug (IND) Application; or
    2. It is authorized for use under the State of California's Right to Try Act; and
    3. Its use is consistent with its FDA-approved IND Application or the State of California's Right to Try Act;
C. Additional criteria that will be considered in the adjudication process include:
    1. Conventional therapy will not adequately treat the intended patient's condition;
    2. Conventional therapy will not prevent progressive disability or premature death;
    3. The provider of the proposed service has a record of safety and success with it or equivalent to that of other providers of the investigational services;
    4. Other criteria (e.g., cost and availability) may be considered in the adjudication of a given request in cases in which more than one investigational service is available;
    5. There is reasonable expectation that the investigational service will significantly prolong the patient's life or will maintain or restore a range of physical and social function suited to activities of daily living; and
    6. The service is not being performed as part of a research study protocol. For a beneficiary with cancer who participates in a clinical trial for cancer, California Health and Safety Code (HSC) § 1370.6 requires that all routine patient care costs related to the clinical trial be covered if the beneficiary's CCS-paneled treating physician recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the enrollee. The coverage does not include investigational services that have not been approved by the FDA and that are associated with the clinical trial.

Feedback

Blue Shield of California Promise Health Plan is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract

provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.

Appendix A

State Guidelines/Policy Statement (No changes)	
BEFORE	**AFTER**
Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence PHP_1.01.17 **State Guidelines:** Applicable Medi-Cal guidelines as of the publication of this policy (this guideline supersedes the criteria in the Policy Statement section below): I. Department of Managed Health Care (DMHC) All Plan Letter (APL) Guideline: • N/A II. Department of Health Care Services (DHCS) Provider Manual Guideline: • TAR and Non-Standard Benefits List: Codes 90000 thru 99999 (tar and non cd9) • TAR and Non-Standard Benefits List: Codes E0000 thru E9999 (tar and non cde) • TAR and Non-Standard Benefits List: Codes G0000 thru G9999 (tar and non cdg) The codes listed on the policy are included in the above Provider Manuals; however, there are no specific clinical guidelines. III. Department of Health Care Services (DHCS) All Plan Letter (APL) Guideline: • N/A **Policy Statement:** Any criteria that are not specifically addressed in the above Provider Manuals, please refer to the criteria below.	**Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence PHP_1.01.17** **State Guidelines:** Applicable Medi-Cal guidelines as of the publication of this policy (this guideline supersedes the criteria in the Policy Statement section below): I. Department of Managed Health Care (DMHC) All Plan Letter (APL) Guideline: • N/A II. Department of Health Care Services (DHCS) Provider Manual Guideline: • TAR and Non-Standard Benefits List: Codes 90000 thru 99999 (tar and non cd9) • TAR and Non-Standard Benefits List: Codes E0000 thru E9999 (tar and non cde) • TAR and Non-Standard Benefits List: Codes G0000 thru G9999 (tar and non cdg) The codes listed on the policy are included in the above Provider Manuals; however, there are no specific clinical guidelines. III. Department of Health Care Services (DHCS) All Plan Letter (APL) Guideline: • N/A **Policy Statement:** Any criteria that are not specifically addressed in the above Provider Manuals, please refer to the criteria below.

State Guidelines/Policy Statement (No changes)	
BEFORE	**AFTER**
I. Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) is considered **investigational** as a treatment for **either** of the following: A. Urinary incontinence B. Fecal incontinence	I. Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) is considered **investigational** as a treatment for **either** of the following: A. Urinary incontinence B. Fecal incontinence