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Biofeedback as a Treatment of Urinary Incontinence

Table of Contents

Related Policies (if applicable)
DME101.037 Pelvic Floor Stimulation (PFS) as a Treatment of Urinary or Fecal Incontinence
MED205.035 Percutaneous Tibial Nerve Stimulation (PTNS)
SUR710.008 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
SUR710.018 Sacral Nerve Neuromodulation/Stimulation

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Coverage

Biofeedback, performed by a licensed healthcare professional, **may be considered medically necessary** for the treatment of urinary incontinence.

Biofeedback, using a home biofeedback device (e.g., leva® Pelvic Health System**) is considered not medically necessary** for the treatment of urinary incontinence.

Biofeedback for treatment of urinary frequency in the absence of urinary incontinence **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. The technique involves the feedback of a variety of types of information not commonly available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiologic process in some specific way. Biofeedback has been proposed as a treatment for a variety of diseases and disorders, including anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia. Biofeedback training is done either in individual or group sessions and as a single therapy or in combination with other therapies designed to teach relaxation. A typical program consists of 10 to 20 training sessions of 30 minutes each. Training sessions are performed in a quiet, non-arousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for successful alteration of the physiologic parameter. This feedback may be in the form of signals, such as lights or tone, verbal praise, or other auditory or visual stimuli.

Biofeedback, in conjunction with pelvic floor muscle training, is a possible treatment modality for stress, urge, mixed, and overflow urinary incontinence because it may enhance awareness of body functions and the learning of exercises to train pelvic muscles. Several proposed methods of biofeedback that may be employed for the treatment of urinary incontinence, includes vaginal cones or weights, perineometers, and electromyographic (EMG) systems with vaginal and rectal sensors.

The various forms of biofeedback mainly differ in the nature of the disease or disorder under treatment, the biologic variable that the subject attempts to control, and the information that is fed back to the subject. Biofeedback techniques include peripheral skin temperature feedback, blood-volume-pulse feedback (vasoconstriction and dilation), vasoconstriction training (temporalis artery), and EMG biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication).

Home Biofeedback

Prescription digital therapeutics (PDTs) are a new class of software-based medical devices that are being used and evaluated for a variety of medical and behavioral health conditions.

The leva® Pelvic Digital Health System is a prescription intra-vaginal device designed to rehabilitate and strengthen pelvic floor muscles (PFM) as well as allowing individuals to monitor their progress during pelvic floor muscle training (PFMT*). Leva* is designed to wirelessly facilitate PFMT in women and to transmit real-time performance data through a dedicated mobile application that has been downloaded to the patient's mobile device. (1)

Regulatory Status
A variety of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters." FDA product code: KPI.

leva®Pelvic Digital Health System
In 2018, the leva® Pelvic Digital Health System received FDA 510(k) marketing clearance based on being substantially equivalent to a marketed predicate device. (31) This device interacts with the user via smart phone technology and is FDA cleared for the following indications:

1. Strengthening of the pelvic floor muscles;
2. Rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed, and mild to moderate urgency urinary incontinence in women.

In 2019, the FDA added the following indication for use of the leva® Pelvic Digital Health System to include women with overactive bladder via the 510(k) process. (1)

FDA Product Code: HIR.

Rationale

This medical policy was created in February 2013 and was updated regularly with searches of the PubMed database. The most recent literature update was performed through March 27, 2023.

Medical policies 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 (QOL), 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, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one 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.

Most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have effects separate from those due to biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. For example, relaxation, attention, or suggestion may account for successful results that have been attributed to biofeedback. These effects are nonspecific therapeutic factors, some of which can be considered placebo effects. To demonstrate efficacy of biofeedback for treating incontinence, studies are needed to isolate the effect of biofeedback and demonstrate an improvement in health outcomes compared with other interventions (e.g., relaxation or behavioral therapy alone). In addition, although research has shown that feedback on physiologic processes provided patients with an enhanced ability to control these processes, evidence is needed on the relation between a patient's ability to exert control over the targeted physiologic process and any health benefits of the intervention. The latter finding underscores the importance of seeking controlled studies showing whether use of biofeedback improves disease-related health outcomes, as opposed to physiologic, intermediate outcomes.

Women with Urinary Incontinence

Clinical Context and Therapy Purpose

The purpose of biofeedback with pelvic floor muscle training (PFMT) in women who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does the use of biofeedback with PFMT improve the net health outcome in women with urinary incontinence?

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

Populations

The relevant population of interest is women with urinary incontinence.

Urinary incontinence is a common condition defined as involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects the QOL and treatment decisions. The types of urinary incontinence women may experience include stress, urge, overflow, and functional. Nonsurgical treatment options may include pharmacologic treatment, pelvic muscle exercises, bladder training exercises, electrical stimulation, and neuromodulation.

Interventions

The therapy being considered is biofeedback with PFMT.

Comparators
The following therapy is currently being used to make decisions about urinary incontinence: PFMT without biofeedback.

Outcomes
The general outcomes of interest are symptom improvement (e.g., incontinence episodes) and functional improvement (generally 1-4 treatments per week, for 8-12 weeks). (2)

Table 1. Outcomes Measures for Women With Urinary Incontinence

Measure	Outcome Evaluated	Description	Follow-up Timing
Oxford Grading Scale Pelvic Floor Muscle Function	Functional improvement	Used by physiotherapists to assess muscle strength as graded 0 to 5. (3) 0 = no movement 1 = flicker of movement 2 = through full range actively with gravity counterbalanced 3 = through full range actively against gravity 4 = through full range actively against some resistance 5 = through full range actively against strong resistance	Baseline and at end of therapy (8-12 weeks)
PERFECT Scheme	Functional improvement	A way of measuring pelvic muscle function and strength. PERFECT stands for (4) **P**ower (Modified Oxford Scale) **E**ndurance (how long contraction is held, up to 10 s) **R**epetitions (up to 10 repetitions of a 10-s hold) **F**ast (number of 1-s contractions in a row, up to 10) **E**very **C**ontraction **T**imed (reminder to time every contraction)	Baseline and at end of therapy (8-12 weeks)

s: second(s).

<u>Study Selection Criteria</u>
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.

Systematic Reviews

Zhu et al. (2022) performed a meta-analysis of 17 RCTs in postpartum women with lower urinary tract symptoms. (5) Fifteen studies (N=1965) compared PFMT plus biofeedback and electrical stimulation with PFMT alone. The analysis reported a significantly greater likelihood of achieving a therapeutic effect with combined PFMT plus biofeedback and electrical stimulation versus PFMT alone (risk ratio, 1.20; 95% confidence interval [CI], 1.15 to 1.24; I^2=0%). Pelvic floor muscle strength was also significantly higher with combination therapy (p<.0001), but there was high heterogeneity among studies for this outcome (I^2=66%). Limitations of this analysis include that 6 studies had a high risk of bias, no studies were blinded, there was evidence of publication bias, most studies were conducted in China, and the study's definition of therapeutic effect was not clearly stated.

Wu et al. (2021) conducted a meta-analysis (N=21 studies; 13 RCTs, 8 nonrandomized) of PFMT with electromyographic biofeedback versus PFMT alone in women with stress incontinence or pelvic floor dysfunction. (6) Most studies were conducted in China and none were from the U.S. In an analysis of studies that reported cure and improvement, there was a significant benefit of PFMT with electromyographic biofeedback compared to PFMT alone in patients with both urinary incontinence (odds ratio, 4.82; 95% CI, 2.21 to 10.51; I^2=85.3%; n=11 studies) and pelvic floor dysfunction (odds ratio, 2.81; 95% CI, 2.04 to 3.86; I^2=13.1%; n=6 studies). Analyses of quality of life and quality of sexual life results were limited by substantial heterogeneity (>80%). Limitations of this analysis include an unclear, moderate, or high risk of bias in all studies and use of Kegel exercises only in some studies rather than a complete PFMT program.

In their systematic review, Mateus-Vasconcelos et al. (2018) assessed various physiotherapy methods to strengthen the pelvic floor muscles for women with stress urinary incontinence. (7) Their review included a mix of RCTs, quasi-experimental trials, and systematic reviews -- total of six studies. Only one study (an uncontrolled RCT) included biofeedback a comparator. That study (Pinheiro et al. [2012]) compared the effectiveness of PFMT with biofeedback (group n=6) to PFMT with palpation (group n=5). The exercises for the biofeedback group consisted of achieving the same number of rapid and slow contractions of the same duration as that achieved during the PERFECT scheme, which stands for power, endurance, repetitions, fast contractions, and every contraction timed (eight series). (8) The palpation group strengthened the pelvic floor muscles while a physiotherapist performed palpations on the central perineal tendon and vagina (four sessions). At the end of treatment, there was no statistical difference in improvement between the biofeedback group and the palpation group in power, endurance, or rapidity of contractions. This RCT was limited in its small sample size and lack of control group and masking of assessors.

Moroni et al. (2016) published a systematic review of 37 RCTs evaluating conservative treatment of stress urinary incontinence in women. (9) Five trials (total n=250 women) were identified that compared PFMT plus biofeedback with biofeedback alone. A pooled analysis of 4 studies found significantly more urine loss as measured by a posttreatment pad test with PFMT alone than with PFMT plus biofeedback (mean difference [MD], 0.90; 95% confidence interval [CI], 0.71 to 1.10). Reviewers noted that the difference between groups was likely not clinically significant because there was only about a 1-gram difference. Moreover, the finding was largely due to the effect of 1 study. Results on other outcomes (e.g., QOL, number of incontinence episodes) could not be pooled due to imprecision of the estimates.

In an Agency for Healthcare Research and Quality comparative effectiveness review, Shamliyan et al. (2012) identified 6 RCTs (N=542 patients) comparing PFMT plus biofeedback with PFMT alone. (10) A meta-analysis of these studies did not find a statistically significant difference between interventions in continence rates. When findings were pooled, the relative risk (RR) was 1.27 (95% CI, 0.88 to 1.85). The absolute risk difference was 0.08 (95% CI, -0.03 to 0.19).

In a Cochrane systematic review, Herderschee et al. (2011) assessed RCTs on feedback or biofeedback in conjunction with PFMT for treating urinary incontinence in women. (11) Feedback was defined as verbal feedback by a clinician, whereas biofeedback involved use of an instrument or device. After examining 36 full-text articles, 24 trials met reviewers' eligibility criteria, and 17 contributed data to the analysis of at least 1 primary outcome measure. Sixteen of the 24 trials compared PFMT plus biofeedback with PFMT alone; 9 of them included the same PFMT programs in both groups. The primary outcomes of the review were QOL and improvement or cure. Nine trials used one of several validated quality-of-life instruments; however, only 4 of these reported data in a form amenable to meta-analysis. Thus, QOL results were not pooled. Data were pooled for the other primary outcome (improvement or cure), but there were a sufficient number of studies only for the comparison between PFMT with and without biofeedback. In a pooled analysis of 7 studies, there was a significant reduction in the proportion of women reporting "no improvement or cure" when biofeedback was added to muscle exercise (RR=0.75; 95% CI, 0.66 to 0.86). Reviewers noted that there may have been other differences between groups, such as more frequent contact with a health care professional or a greater number of treatment sessions, which might partially explain the difference between the improvement or cure rates in women who did or did not receive biofeedback. Moreover, when only the outcome "no cure" was examined, there was no significant difference between groups that did and did not receive biofeedback (5 studies; RR=0.92; 95% CI, 0.81 to 1.05). Among secondary outcomes, a pooled analysis of 7 trials did not find a significant difference in leakage episodes in a 24-hour period after treatment (MD = -0.01; 95% CI, -0.21 to 0.01). For the outcomes frequency and nocturia, data could not be combined but reviewers reported that the pattern was one of no difference between groups.

Randomized Controlled Trials

Selected larger RCTs that compared PFMT with and without biofeedback are summarized in this section. Hagen et al. (2020) conducted a multicenter RCT in 600 women with stress or mixed urinary incontinence. (12) Participants were randomized to 16 weeks of PFMT with

electromyographic biofeedback or PFMT alone. Both groups received supervised PFMT during clinic appointments and a home PFMT regimen. The mean number of appointments attended was about 4 in both groups. Urinary incontinence symptoms (self-reported at month 24 via the International Consultation on Incontinence Questionnaire on Urinary Incontinence Short Form [ICIQ-UI-SF]) were similar in both groups (mean difference, -0.09; 95% CI, -0.92 to 0.75; p=.84). The ICIQ-UI-SF scores were also similar between groups at earlier times (6 and 12 months). At 24 months, the proportion of patients who achieved the study's definition of cure, improvement, and symptoms that were very much better or much better was similar between groups. Pelvic floor muscle strength and endurance was assessed at 6 months, with similar findings in both groups. A limitation of this study is the short duration of the intervention compared to the length of follow-up.

Williams et al. (2006) published a study that included 238 women who had failed a primary behavioral therapy (e.g., advice on fluid intake, bladder reeducation, weight loss) for 3 months. (13) They were randomized to intensive PFMT (n=79), PFMT using vaginal cones (n=80), or continued behavioral therapy (n=79) for 3 months. Patients in all 3 groups were seen in the clinic every other week for 8 weeks and at 12 weeks. At 12 weeks, all 3 groups had moderate reductions in incontinence episodes and some improvement in voiding frequency; there were no statistically significant differences in outcomes among the 3 groups. For example, mean reduction in incontinence episodes over 24 hours was -1.03 in the PFMT group, -0.28 in the vaginal cone group, and -0.59 in the control group (p=0.2).

Burgio et al. (2002) reported on findings of an RCT with 222 women who had urge or mixed incontinence. (2) Interventions in this 3-armed trial were as follows: 1) 74 patients who received behavioral training along with digital palpation instruction (no biofeedback) and 4 office visits in 8 weeks; 2) 73 patients who received biofeedback-assisted behavioral training and 4 office visits in 8 weeks; and 3) 75 patients who were given a self-help book with no office visits (control condition). Behavioral training in the 2 intervention groups included teaching pelvic floor exercises as well as skills and strategies for reducing incontinence. Patients in all groups kept bladder diaries through the 8-week treatment period. In an intention-to-treat analysis, the mean reduction in incontinence episodes was 69.4% in the behavioral training plus verbal feedback group, 63.1% in the behavioral training plus biofeedback group, and 58.6% in the control group. The 3 groups did not differ significantly from one another (p=0.23). In addition, QOL outcomes were similar in the 3 groups.

Other RCTs comparing the efficacy of PFMT alone with PFMT with biofeedback have been published. (14, 15, 16, 17) They tended not to find statistically significant differences in outcomes between interventions; however, sample sizes were small (i.e., <25 per group) and thus the studies might have been underpowered.

Section Summary: Women with Urinary Incontinence

Numerous RCTs and several systematic reviews have evaluated biofeedback as a treatment of urinary incontinence in women. Trial reporting methodologies varied, and many did not isolate the potential contribution of biofeedback. A comparative effectiveness review did not find a

statistically significant difference in continence rates when patients received PFMT with or without biofeedback. Other systematic reviews evaluating biofeedback and/or verbal feedback as part of treatment for urinary incontinence found improvement in some outcomes (e.g., improvement or cure, urine volume) but not others (e.g., cure, leakage episodes).

Men with Prostatectomy-Related Urinary Incontinence

Clinical Context and Therapy Purpose

The purpose of biofeedback with PFMT in men who have post-prostatectomy urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does the use of biofeedback with PFMT improve the net health outcome in men with post-prostatectomy urinary incontinence?

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

Populations

The relevant population of interest is men with post-prostatectomy urinary incontinence.

Interventions

The therapy being considered is biofeedback with PFMT.

Comparators

The following therapy is currently being used to make decisions about urinary incontinence: PFMT without biofeedback.

Outcomes

The general outcomes of interest are symptom reduction and functional outcomes (approximately eight weeks). (18)

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.

Systematic Reviews

Hsu et al. (2016) published a systematic review of PFMT with biofeedback in men who had radical prostatectomy. (19) Thirteen trials met reviewers' inclusion criteria. However, on inspection, not all trials included a biofeedback intervention, and other trials did not compare

PFMT alone to PFMT plus biofeedback. Thus, conclusions about the added efficacy of biofeedback cannot be determined from the results of this meta-analysis.

A Cochrane review by Anderson et al. (2015) assessed conservative treatments for post-prostatectomy urinary incontinence. (20) Reviewers included a comparison of PFMT (with or without biofeedback) and sham or no treatment. They did not evaluate the potential added value of biofeedback (i.e., by comparing PFMT with biofeedback and PFMT without biofeedback).

Previously, MacDonald et al. (2007) conducted a systematic review of PFMT to improve urinary incontinence after radical prostatectomy. (21) Reviewers identified 3 studies (281 men) that compared biofeedback and PFMT with muscle training alone (written/verbal instructions provided). Study findings were not pooled; none of the individual trials included in the review found a statistically significant difference in outcomes between groups.

Randomized Controlled Trials

Goode et al. (2011) reported on an RCT evaluating biofeedback and PFMT in 208 men with urinary incontinence persisting at least 1 year after radical prostatectomy. (18) Men with pre-prostatectomy incontinence were excluded. Participants were randomized to 1 of 3 groups: 8 weeks of behavioral therapy (PFMT and bladder control exercises; n=70), behavioral therapy plus biofeedback and electric stimulation (n=70), and a delayed-treatment control group (n=68). The biofeedback and electric stimulation intervention, called "behavior-plus," consisted of in-office electric stimulation with biofeedback using an anal probe and daily home pelvic floor electrical stimulation. After 8 weeks, patients in the 2 active treatment groups were given instructions for a maintenance program of pelvic floor exercises and fluid control and were assessed at 6 and 12 months. The primary efficacy outcome was reduction in the number of incontinent episodes at 8 weeks, as measured by a 7-day bladder diary. A total of 176 (85%) of 208 randomized men completed the 8 weeks of treatment. In an intention-to-treat analysis of the primary outcome, the mean reduction in incontinent episodes was 55% (28-13 episodes/week) in the behavioral therapy group, 51% (26-12 episodes/week) in the behavior-plus group, and 24% (25-20 episodes/week) in the control group. The overall difference between groups was statistically significant (p=0.001), but the behavior plus intervention did not result in a significantly better outcome than behavioral therapy alone. Findings were similar on other outcomes. For example, at the end of 8 weeks, there was a significantly higher rate of complete continence in the active treatment groups (11/70 [16%] in the behavior group, 12/70 [17%] in the behavior-plus group) than the control group (4/68 [6%]), but the group receiving biofeedback and electrical stimulation did not have a significantly higher continence rate than the group receiving behavioral therapy alone.

Section Summary: Post-Prostatectomy Urinary Incontinence

An RCT and systematic reviews have evaluated the efficacy of biofeedback with PFMT for treatment of prostatectomy-related urinary incontinence compared with PFMT without biofeedback. Results of these data are mixed.

Planned Radical Prostatectomy

Clinical Context and Therapy Purpose

The purpose of biofeedback with PFMT in men who are scheduled for radical prostatectomy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does the use of biofeedback with PFMT improve the net health outcome in men scheduled for radical prostatectomy?

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

Populations

The relevant population of interest is men scheduled for radical prostatectomy.

Interventions

The therapy being considered is biofeedback with PFMT.

Comparators

The following therapy is currently being used to make decisions about urinary incontinence: PFMT without biofeedback.

Outcomes

The general outcomes of interest are symptom prevention and functional outcomes (starting two-four weeks before the procedure and continuing after; follow-up three to twelve months). (22, 23, 24, 25)

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.

Randomized Controlled Trials

Several trials have evaluated the use of pre- or perioperative biofeedback for patients undergoing radical prostatectomy for prevention of postoperative urinary incontinence. Oh et al. (2020) randomized 84 patients undergoing robot-assisted laparoscopic radical prostatectomy to receive biofeedback with an extracorporeal perineometer plus PFMT or PFMT alone. (22) Although the average urine loss volume was lower in the biofeedback plus PFMT group compared to PFMT alone at month 1 after catheter removal (p=0.028), there was no difference between groups at months 2 or 3 after catheter removal. At study end (month 3),

the percentage of continent patients was not significantly different between the biofeedback plus PFMT group (67.5%) and PFMT alone (61.9%).

Tienforti et al. (2012) reported on an RCT comparing biofeedback (sessions before and after surgery) plus pelvic floor muscle exercises with a control intervention PFMT alone in patients undergoing radical prostatectomy. (23) The trial enrolled 34 patients, 32 of whom (16 in each group) were available for the final 6-month analysis. By 6 months, 10 (62.5%) of 16 patients in the treatment group and 1 (6.3%) of 16 patients in the control group were continent (p=0.002). The mean number of incontinence episodes per week was also significantly lower in the intervention group (2.7) than in the control group (13.1) at 6 months (p=0.005).

A trial by Wille et al. (2003) randomized 139 men prior to radical prostatectomy to 1 of 3 groups. (24) Group 1 received verbal and written instructions about PFMT from a physical therapist. Group 2 received PFMT instruction and instruction on using an electrical stimulation device. Group 3 received the previous 2 intervention components and training on using biofeedback with the electrical stimulation device. Patients had regular contact with a health care provider for the first 5 weeks after surgery. In the immediate postsurgical period, 20.5% in group 1, 22.9% in group 2, and 20.7% in group 3 were continent (p=0.815). After 6 and 12 months, continence rates remained similar among the groups. Twelve-month continence rates were 88% in group 1, 81% in group 2, and 88.6% in group 3 (p=0.524).

Bales et al. (2000) randomized 100 men scheduled to undergo radical prostatectomy to PFMT plus biofeedback intervention (n=50) or to a control group (n=50) that received written and brief verbal instructions performing PFMT. (25) The intervention consisted of a single session with a trained nurse, 2 to 4 weeks before surgery. Three men dropped out of the PFMT plus intervention group. At 6 months after surgery, there was no difference between groups; the incidence of urinary incontinence was 94% (44/47) in the PFMT plus biofeedback group and 96% (948/40) in the control group.

Tables 2 and 3 more fully summarize key trial characteristics and results of these trials.

Table 2. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Oh et al. (2020) (22)	South Korea	1	2015-2017	84 patients undergoing robot-assisted laparoscopic radical prostatectomy	Biofeedback (using extracorporeal device [Anykegel]) and PFMT after catheter removal (n=42)	PFMT after catheter removal (n=42)

Tienforti et al. (2012) (23)	Italy	1	2009-2010	38 patients who underwent standard open retropubic radical prostatectomy for prostate cancer	Biofeedback (using anal probe [PelveenCare]) after catheter removal and PFMT (n=16)	Verbal and written instructions on PFMT to be performed at home (n=16)
Wille et al. (2003) (24)	Germany	1	1999-2001	139 patients who underwent radical retropubic prostatectomy	Biofeedback (using anal probe) plus PFMT and electrical stimulation (n=46)	Comparator 1: Verbal and written instructions about postoperative PFMT with intensive physiotherapy (n=47) Comparator 2: PFMT and electrical stimulation (n=46)
Bales et al. (2000) (25)	U.S.	1	NR	100 patients undergoing radical retropubic prostatectomy	Biofeedback and instructions on PFMT (n=50)	Verbal and written instructions on PFMT (n=50)

NR: not reported; PFMT: Pelvic floor muscle training; U.S.: United States.

Table 3. Summary of Key Randomized Controlled Trial Results

Study (Year)	**Final N**	**Continence**	**Average 24-Hour Urine Loss**
Oh et al. (2020) (22)		***Loss of 0 g of urine on a 24-hour pad test***	
Biofeedback + PFMT	40	27/40 (67.5%) (3 months)	71.0 ± 48.0 g (month 1), 59.7 ± 83.4 g (month 2), 38.8 ± 141.2 g (month 3)
PFMT alone	42	26/42 (61.9%) (3 months)	120.8 ± 132.7 g (month 1), 53.1 ± 96.6 g (month 2), 19.5 ± 57.2 (month 3)

P value		0.649		0.028 (month 1), 0.744 (month 2), 0.415 (month 3)
Tienforti et al. (2012) (23)		***ICIQ-UI score of 0***		
Biofeedback + PFMT	16	6/16 (month 1), 8/16 (month 2), 10/16 (month 3)		NR
PFMT alone	16	0/16 (month 1), 1/16 (month 2), 1/16 (month 3)		NR
P value		0.02 (month 1), 0.01 (month 2), 0.002 (month 3)		NR
Wille et al. (2003) (24)		***Assessed by questionnaire***	***Assessed by 20-minute pad test[a]***	
Biofeedback + PFMT + electrical stimulation	46	20.7% (immediate postsurgical period), 88.6% (12 months)	33% (immediate postsurgical), 90.5% (12 months)	NR
PFMT+ electrical stimulation	46	22.9% (immediate postsurgical period), 81% (12 months)	36.4% (immediate postsurgical), 82% (12 months)	NR
PFMT	47	20.5% (immediate postsurgical period), 88% (12 months)	29% (immediate postsurgical), 76.7% (12 months)	NR
P value		0.815 (immediate postsurgical), 0.524 (12 months)	0.822 (immediate postsurgical), 0.236 (12 months)	NR
Bales et al. (2000) (25)		**Use of 1 or less pad per day**		
Biofeedback + PFMT	47	44/47 (94%) (6 months)		NR
PFMT alone	50	48/50 (96%) (6 months)		NR
P value		0.596		NR

[a] The 20-minute pad test assesses continence by performing various activities with a bladder volume of 75% while wearing a pad to collect urine.

ICIQ-UI: International Consultation on Incontinence Questionnaire on Urinary Incontinence; NR: not reported; PFMT: pelvic floor muscle training.

Tables 4 and 5 display notable limitations in the trials. Major limitations include a limited number of outcomes assessed by trials (e.g., not including safety data), an inability to blind patients and/or the outcome assessment due to the nature of the intervention, unclear methods of allocation concealment, and missing power calculations. Although most studies did not include safety endpoints, biofeedback is generally considered a safe treatment. (23)

Table 4. Study Relevance Limitations

Study; Trial	Population[a]	Intervention[b]	Compartor[c]	Outcomes[d]	Follow-up[e]
Oh et al. (2020) (22)				1. Key health outcomes not addressed; 3. No CONSORT reporting of harms	
Tienforti et al. (2012) (23)			3. Delivery not similar intensity as intervention		
Wille et al. (2003) (24)				1. Key health outcomes not addressed; 3. No CONSORT reporting of harms	
Bales et al. (2000) (25)			3. Delivery not similar intensity as intervention	1. Key health outcomes not addressed; 3. No CONSORT reporting of harms	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Limitations

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Complete-ness[d]	Power[e]	Statistical[f]
Oh et al. (2020) (22)		1. Not blinded to treatment assignment; 2. Not blinded outcome assessment				
Tienforti et al. (2012) (23)		1. Not blinded to treatment assignment				
Wille et al. (2003) (24)	3. Allocation concealment unclear	1. Not blinded to treatment assignment; 2. Not blinded outcome assessment			1. Power calculations not reported	
Bales et al. (2000) (25)	3. Allocation concealment unclear	1. Not blinded to treatment assignment			1. Power calculations not reported	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3.

Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Section Summary: Men Scheduled for Radical Prostatectomy

RCTs have evaluated the efficacy of biofeedback with PFMT for prevention of prostatectomy-related urinary incontinence compared with PFMT without biofeedback. These trials generally did not report consistently improved outcomes with biofeedback added to the intervention.

Children with Dysfunctional Elimination Syndrome

In 2010, Palmer published an article with an overview of bladder control and pediatric voiding dysfunction. The author addressed biofeedback and concluded that biofeedback has been shown to be very effective in children to correct incontinence secondary to dysfunctional voiding, as well as in treating giggle incontinence and to help resolve vesicoureteral reflux. (26)

In 2008, Kaye and Palmer published an article evaluating the efficacy of biofeedback with and without animation in treating dysfunctional voiding and urinary symptoms. The comparison reported included 120 girls with urinary complaints and exhibited dysfunctional voiding on electromyography uroflow. The authors noted their comparison included the last 60 cases of biofeedback using electromyography tracing alone (non-animated) were compared with the first 60 cases using the Urostym Pediflow program (animated). The evaluation of the 2 groups included improvement in post-void residual volume after treatment, and time to resolution of symptoms and dysfunctional voiding. Results reported included the following: Dysfunctional voiding resolved in 95% of patients in both groups. Post-void residual reduction was similar, namely from 35% to 9% of pre-void volume in the nonanimated group, and from 28% to 8% in the animated group. Children in the animated biofeedback group achieved success in significantly fewer sessions (3.6) than those undergoing nonanimated biofeedback (7.6, t test $p < 0.05$). The authors concluded that despite their proved experience with nonanimated biofeedback systems and inexperience with an animated system, animated biofeedback systems yielded similar results in a significantly shorter time. Animated and nonanimated biofeedback is efficacious in the treatment of dysfunctional voiding and its symptoms. (27)

In 2011, a published article from Kajbafzadeh et al. assessed the efficacy of animated biofeedback in children with dysfunctional elimination syndrome. Eighty children were randomly assigned to two groups to undergo either conservative therapy or animated biofeedback. Group A had 40 patients and were treated with animated biofeedback along with pelvic floor muscles exercises and behavioral modification (hydration, high fiber diet, scheduled voiding). Group B had 40 patients and were treated with behavioral modification only. Results reported by the authors included animated biofeedback therapy was more efficient than nonbiofeedback management with regards to objective and subjective voiding problems and bowel dysfunction ($p<0.05$). The following conclusions were indicated by the authors animated biofeedback effectively treats bowel and voiding dysfunction in children with dysfunctional voiding. (28)

Desantis et al. (2011) conducted a literature search to analyze if biofeedback was an effective method to treat children less than 18 years of age for dysfunctional elimination syndrome. The authors noted articles were retrieved for data abstraction and quality assessment. Primary outcomes were urinary tract infections (UTIs) and daytime incontinence. Twenty-seven studies were evaluated (1 RCT, and 26 case-series). The authors results indicated the pooled estimate showed 83% (95% CI: 79%-86%) and 80% (95% CI: 76%-85%) improvement in UTI and daytime incontinence, respectively. Although not statistically significant, the RCT favored biofeedback over standard therapy. The authors of the article indicated in their conclusions that biofeedback is an effective, non-invasive method of treating dysfunctional elimination syndrome, and approximately 80% of children benefited from this treatment. Also noted in the conclusion was, most reports were of low level of evidence and studies of more solid design such as RCT should be conducted. (29)

Fazeli et al. (2015) conducted a systematic review of the literature to assess the effects of biofeedback as adjunctive therapy for symptoms of nonneuropathic voiding disorders in children up to age 18 years. (30) Five eligible studies were included in the systematic review, of which 4 (382 participants) were pooled in the meta-analysis based on available outcomes data. The overall proportion of cases with resolved incontinence at month 6 was similar in the biofeedback and control groups (odds ratio [OR] 1.37 [95% CI 0.64 to 2.93], risk difference [RD] 0.07 [-0.09, 0.23]). There was also no significant difference in mean maximum urinary flow rate (mean difference 0.50 ml, range -0.56 to 1.55) or likelihood of urinary tract infection (OR 1.30 [95% CI 0.65 to 2.58]). Current evidence does not support the effectiveness of biofeedback in the management of children with nonneuropathic voiding disorders. More high quality, RCTs are needed to better evaluate the effect of biofeedback.

Qi et al. (2022) performed a systematic review and meta-analysis to assess the efficacy of biofeedback treatment for children with non-neurogenic voiding dysfunction (NVD). (32) Fifteen studies and 1274 patients were included in the systematic review, seven RCTs and 539 patients were included in the meta-analysis. The meta-analysis showed efficacy of biofeedback treatment in the following aspects, 1) relieving urinary tract infections (RR: 1.71, 95% CI: 1.11 to 2.64), 2) reducing post void residual (PVR) (mean difference [MD]: 9.51, 95% CI:2.03 to 16.98), 3) increasing maximum urine flow rate (MD: 4.28, 95% CI: 2.14 to 6.42) and average urine flow rate (MD: 1.49, 95% CI: 0.53 to 2.46), 4) relieving constipation (risk ration [RR]: 1.59, 95% CI: 1.12 to 2.26),5) improving abnormal voiding pattern (RR: 1.75, 95% CI: 1.30 to 2.36) and abnormal electromyography (EMG) during voiding (RR: 1.55, 95% CI: 1.25 to 1.91). The improvement of UTI symptoms, maximum urine flow rate and average urine flow rate took a longer time (12 months). In terms of daytime incontinence (RR: 1.20, 95% CI [0.96, 1.50], p = 0.11), nighttime incontinence (RR: 1.20, 95% CI [0.62,2.32], p = 0.58), no significant difference was found between biofeedback treatment and standard urotherapy. The qualitative analysis showed that biofeedback treatment was beneficial for NVD. The authors' concluded that compared with standard urotherapy, biofeedback treatment is effective for some symptoms, such as UTI and constipation, and can improve some uroflowmetric parameters, such as PVR. Biofeedback treatment seems to have a better long-term effect.

UpToDate (33)
UpToDate notes the management of a child with bladder dysfunction, defined as any abnormality in either the filling and/or emptying of the bladder, is primarily directed at improving symptoms and avoiding kidney damage. Therapeutic considerations include the underlying cause of bladder dysfunction including behavioral and neurodevelopment etiologies, the age of the patient, symptom duration and severity, the motivation and attention span of the patient and family, and the presence of potential risk factors for kidney injury such as recurrent urinary tract infections or vesicoureteral reflux.

Several limitations were noted concerning data on effective treatment of bladder dysfunction in children due to flaws in study design. One limitation noted was a lack of consensus among experts of the definition of successful treatment for bladder dysfunction. UpToDate noted that the International Children's Continence Society (ICCS) defined treatment outcomes for research purposes. They further note that this stratified set of definitions has also been used clinically and is based upon reducing the rate of symptoms as follows:

- Nonresponse: 0 to 49 percent decrease in symptoms
- Partial response: 50 to 89 percent decrease in symptoms
- Response: 90 to 99 percent decrease in symptoms
- Full response: 100 percent decrease or less than one symptom occurrence monthly.

Conservative management – Management of a child with bladder dysfunction, defined as any abnormality in either the filling and/or emptying of the bladder, is directed at improving the child's symptoms and avoiding kidney damage. In their practice, a stepped approach is used starting with the least invasive therapy (i.e., voiding behavior modification), and if the patient remains unresponsive, moving to more invasive and/or costly interventions (i.e., medications or biofeedback). The initial therapeutic measures include voiding behavior modification with timed voiding schedules, and treatment of constipation, if present.

Section Summary: Children with Dysfunctional Elimination Syndrome
Several studies have evaluated the efficacy of biofeedback for children with dysfunctional elimination syndrome. Systematic reviews of studies were noted. Outcome results noted in these reviews were mixed.

Home Biofeedback
Keyser et al. (2022) performed a retrospective cohort study of real-word data from users of a prescription digital therapeutic (pDTx) in reducing urinary incontinence (UI) symptoms. (34) Data between July 1, 2020‑December 31, 2021, was from users of a pDTx designed to guide pelvic floor muscle training (PFMT). The primary outcome was UI symptom change as reported via in-app Urogenital Distress Inventory (UDI-6). Included subjects were female, ≥ 18 years with a diagnosis of stress, urgency, or mixed UI who completed the UDI-6 at baseline and 8 weeks. Of 532 women with UI, 265 (50%) met criteria and were included in the analysis. Mean age was 51.2 ± 11.5 years (range 22-84, *N* = 265). Mean body mass index (BMI) was 27.3 ± 6.2 kg/m^2 (range 15.2-46.9, N = 147). Most participants had stress UI (59%) followed by mixed UI

(22%), urgency UI/OAB (11%), and unspecified UI (8%). UDI-6 scores improved by 13.90 ± 15.53 ($p \leq 0.001$); 62% met or exceeded minimum clinical important difference (MCID). Device-reported PFMT adherence was 72% at 4 weeks and 66% at 8 weeks (100% = 14 uses/week). Participants in each diagnosis category reported significant improvement on UDI-6 score from baseline to 8 weeks. No association between UDI-6 score improvement and adherence category, age, BMI, or UI subtype was identified. The authors concluded that this study demonstrates effectiveness of a pDTx in reducing UI symptoms in a real-world setting. Users achieved statistically and clinically significant symptom improvement over an 8-week period.

Weinstein et al. (2023) evaluated 6- and 12-months efficacy of an 8-week regimen of pelvic floor muscle training guided by a motion-based digital therapeutic device compared with a standard home program in the treatment of stress urinary incontinence (SUI) and stress-predominant mixed urinary incontinence (MUI). (35) The primary virtual trial was conducted from October 2020 to March 2021; 363 women with SUI or stress-predominant MUI were randomized to complete pelvic floor muscle training using the device (intervention group) or a standard home pelvic floor muscle training program (control group) for 8 weeks. Primary outcomes included change in UDI-6 (Urogenital Distress Inventory, Short Form) score and SUI episodes on a 3-day bladder diary. The PGI-I (Patient Global Impression of Improvement) was also assessed, with "much better" and "very much better" responses considered as improvement. In this planned secondary analysis, symptom and adherence data were collected in follow-up at 6 and 12 months. A modified intention-to-treat analysis was performed using Student's t tests and $\chi 2$ tests as appropriate. The results of the 299 participants analyzed at 8 weeks noted the following: 286 (95.7%) returned 6- and 12-month data (151 in the control group, 135 in the intervention group). Mean age was 51.9±12.8 years, and mean body mass index (BMI) was 31.8±7.4; 84.6% of participants were parous, and 54.9% were postmenopausal. Mean change in UDI-6 score from baseline to 6 and 12 months was significantly greater in the intervention group than in the control group (20.2±20.9 vs 14.8±19.5, *P*=.03 and 22.7±23.3 vs 15.9±20.3, *P*=.01, respectively). Participants in the intervention group had more than twice the odds of reporting improvement on the PGI-I compared with participants in the control group (OR 2.45, 95% CI1.49-4.00). The authors concluded that pelvic floor muscle training guided by a motion-based digital therapeutic device yielded significantly greater urinary incontinence symptom improvement compared with a standard home pelvic floor muscle training program at 6 and 12 months, although continued improvement waned over time. This technology may facilitate pelvic floor muscle training access and adherence for women with SUI and stress-predominant MUI and represents an effective modality for scaling first-line care. The authors also note the following limitations: lack of physical examination and other objective measures of pelvic floor muscle performance at baseline and follow-up. Additionally, bladder diaries were not collected at 6 or 12 months to enable comparison of number of UI episodes reported during the active study period. Also, although they we were able to collect information regarding continued use for participants in the intervention group due to reporting from the device, the authors were not able to collect parallel information for participants in the control group. The authors note that although this limited their ability to understand the presence or absence of continued pelvic floor muscle training in the control group, it is inherent in the design of the control group and typical for the use of home pelvic floor muscle training.

Other studies concerning home biofeedback were reviewed. There was a paucity of literature available, and these studies included small numbers of participants as well as short follow-up times. (Barnes et al. 2021 [41], and Smith et al. 2000 [42]). Another study (Hagen et al. 2020 [43]) included 600 participants from February 2014 to July 2016 that were randomized 300 to pelvic floor muscle training (PFMT) plus electromyographic biofeedback and 300 to PFMT alone. Participants, therapy providers and researchers were not blinded to group allocation. Six-month pelvic floor muscle assessments were conducted by a blinded assessor. The authors concluded that there was no evidence of a difference between biofeedback pelvic floor muscle training and basic pelvic floor muscle training.

Section Summary: Home Biofeedback

For women who have urinary incontinence symptoms who receive home biofeedback, the studies reviewed included one retrospective cohort study of real-word data from users of a prescription digital therapeutic; a study that reported 6- and 12-month planned follow-up from a prospective, randomized controlled trial, as well as 2 RCTs and a self-directed home biofeedback treatment study. The studies all used some form of a continence assessment form/questionnaire (e.g., UDI-6 scores [Urogenital Distress Inventory, short form] or International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form) to evaluate outcomes of treatment. There were several limitations noted for the studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome for this emerging area of healthcare.

Summary of Evidence

For individuals who have urinary incontinence (women) who receive biofeedback with pelvic floor muscle training (PFMT), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life (QOL). A comparative effectiveness review did not find a statistically significant difference in continence rates when patients received PFMT with or without biofeedback. Other systematic reviews evaluating biofeedback and/or verbal feedback as part of treatment for urinary incontinence found improvement in some outcomes but not others.

For individuals who have post-prostatectomy urinary incontinence, the evidence includes an RCT and systematic reviews that compared PFMT with or without biofeedback. Relevant outcomes are symptoms, functional outcomes, and QOL. Results of these data were mixed and did not consistently report significantly improved outcomes when biofeedback was added to the intervention.

For individuals who will undergo radical prostatectomy, RCTs have evaluated the efficacy of biofeedback with PFMT compared with PFMT without biofeedback for prevention of prostatectomy-related urinary incontinence. These trials generally reported poor outcomes with biofeedback added to the intervention. The timing and delivery of the intervention were not well-defined.

For children with dysfunctional elimination syndrome, several studies have evaluated the efficacy of biofeedback. Study findings were inconsistent.

For individuals who have urinary incontinence who received home biofeedback for PMFT, the evidence includes cohort studies and RCTs. Relevant outcomes are symptoms, functional outcomes and QOL. Results of these data were mixed and did not consistently report improved outcomes. Results reported had varying follow-up times and varying sizes of participants. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Urological Association et al.

In their guidelines on treatment of stress urinary incontinence in women, the American Urological Association and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (2017) recommended offering several treatment options including PFMT with biofeedback: "Pelvic floor muscle training and incontinence pessaries are appropriate for patients interested in pursuing therapy that is less invasive than surgical intervention. Pelvic floor physical therapy can be augmented with biofeedback in the appropriate patient. The patient must be willing and able to commit to regularly and consistently performing pelvic floor training for this to be successful." (36)

The American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction Guideline (2019) on treating incontinence after prostate treatment states that the RCTs that were assessed differed on the regimen of pelvic floor muscle training, with some studies including biofeedback or electrical stimulation. (37) Guideline Statement 16 recommends pelvic floor muscle exercises or pelvic floor muscle training, but biofeedback is not mentioned as part of the treatment.

American College of Obstetricians and Gynecologists and the American Urogynecologic Society

The American College of Obstetricians and Gynecologists and the American Urogynecologic Society (issued 2015; reaffirmed 2018) issued a practice bulletin on urinary incontinence in women. (38) The practice bulletin states, "Pelvic muscle exercises may be used alone or augmented with bladder training, biofeedback, or electrical stimulation".

National Institute for Health and Clinical Excellence

In 2019, the National Institute for Health and Care Excellence updated its guidance on the management of urinary incontinence in women. (39) Recommendations on biofeedback included: "do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training" and "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".

Medicare National Coverage

In 2001, the Centers for Medicare & Medicaid issued a national coverage determination. (40) It states:

"This policy applies to biofeedback therapy rendered by a practitioner in an office or other facility setting.

Biofeedback is covered for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Biofeedback-assisted PME incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of PME.

A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

Home use of biofeedback therapy is not covered."

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in June 2022 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	90875, 90876, 90901, 90912, 90913
HCPCS Codes	E0746, S9002

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
02/01/2025	Reviewed. No changes.
6/15/2023	Document updated with literature review. The following changes were made to Coverage: The experimental, investigational and/or unproven statement for biofeedback was changed to: Biofeedback, performed by a licensed healthcare professional, may be considered medically necessary for the treatment of urinary incontinence. Biofeedback, using a home biofeedback device (e.g., leva® Pelvic Health System) is considered not medically necessary for the treatment of urinary incontinence. Biofeedback for treatment of urinary frequency in the absence of urinary incontinence is considered experimental, investigational and/or unproven. The following references were added: 1, 5-6, 12, 16-17, 31-35, 41-43; others updated and one reference removed.
10/15/2022	Reviewed. No changes.
12/01/2021	Document updated with literature review. Coverage unchanged. The following references were added/updated: 17 and 28.
10/15/2020	Reviewed. No changes.
11/15/2019	Document updated with literature review. Coverage unchanged. The following references were added/updated: 3-6, 20-21, 23, and 32.
06/15/2018	Reviewed. No changes.
06/01/2017	Document updated with literature review. Coverage unchanged.
12/01/2016	Reviewed. No changes.
10/01/2015	Document updated with literature review. Coverage unchanged.
12/01/2014	Reviewed. No changes.
02/01/2013	New medical document. Biofeedback is considered experimental, investigational and unproven as a treatment of urinary incontinence. Coverage is unchanged. (This topic was previously addressed on PSY301.007 Biofeedback and Neurofeedback.)