2.01.27	Biofeedback as a Treatment of Urinary Incontinence in Adults		
Original Policy Date:	January 11, 2008	**Effective Date:**	December 1, 2024
Section:	2.0 Medicine	**Page:**	Page 1 of 22

Policy Statement

I. Biofeedback in the outpatient setting is considered **investigational** as a treatment of urinary incontinence in adults.

II. Unsupervised home use of biofeedback for treatment of urinary incontinence is considered **investigational**.

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

Policy Guidelines

Coding
See the Codes table for details.

Description

Biofeedback is a technique to teach individuals self-regulation of physiologic processes not generally considered to be under voluntary control; a variety of approaches and devices are available. Biofeedback, in conjunction with pelvic floor muscle training, is proposed as a treatment of urinary incontinence.

Related Policies

- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
- Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
- Percutaneous and Subcutaneous Tibial Nerve Stimulation
- Sacral Nerve Neuromodulation/Stimulation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 1 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."

The leva® Pelvic Heath system uses motion sensor technology to provide biofeedback through use of an intravaginal device worn pelvic during training with connection to a smartphone app. The device received FDA approval in 2022 for fecal incontinence, urinary incontinence, and strengthening of the pelvic muscle floor.

FDA product code: KPI; HIR.

Rationale

Background

Biofeedback

Biofeedback is intended to teach individuals self-regulation of certain physiologic processes not normally considered to be under voluntary control. The technique involves feedback on a variety of types of information not commonly available to the individual , followed by a concerted effort on the part of the individual 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, nonarousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for the 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 biofeedback methods may be employed to treat urinary incontinence, including vaginal cones or weights, perineometers, and electromyographic 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 electromyographic biofeedback; they may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication).

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 individuals 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.

Several methodologic difficulties arise in assessing biofeedback.[1,] 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 the 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 has enhanced individuals' ability to control these processes, the evidence is needed on the relationship between a individual'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 the use of biofeedback improves disease-related health outcomes, as opposed to physiologic, intermediate outcomes.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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

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 quality of life 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 to 4 treatments per week, for 8 to 12 weeks).[2,] Outcome measures for women with urinary incontinence are listed in Table 1.

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 to 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 to 12 weeks)
Urogenital Distress Inventory (UDI-6)	Lower urinary tract symptoms	6-item questionnaire assessing:[5,] • Urination frequency • Urine leakage related to urgency • Urine leakage related to physical activity • Small amounts of urine leakage • Difficulty with bladder emptying • Lower abdomen or genitalia discomfort Scored on a 0-100 point scale.	NR

s: second(s).

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

Zhu et al (2022) performed a meta-analysis of 17 RCTs in postpartum women with lower urinary tract symptoms.[6,] 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 6 studies with high risk of bias, lack of blinding, evidence of publication bias, most studies were conducted in China, and the definition of therapeutic effect was not clearly stated in individual studies.

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.[7,] 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.[8,] Their review included a mix of RCTs, quasi-experimental trials, and systematic reviews—a total of 6 studies. Only 1 study (an uncontrolled RCT) included biofeedback as 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 (8 series).[9,] The palpation group strengthened the pelvic floor muscles while a physiotherapist performed palpations on the central perineal tendon and vagina (4 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.[10,] Five trials (N=250 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, 0.90; 95% 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 a single study. Results on other outcomes (e.g., quality of life, number of incontinence episodes) could not be pooled due to the imprecision of the estimates.
In an Agency for Healthcare Research and Quality comparative effectiveness review, Shamliyan et al (2012) identified 6 RCTs (N=542) comparing PFMT plus biofeedback with PFMT alone.[11,] A meta-analysis of these studies did not find a statistically significant difference between interventions in incontinence rates. When the findings were pooled, the relative risk 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.[12,] 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 quality of life and improvement or cure. Nine trials used one of several validated quality of life instruments; however, only 4 of them reported data in a form amenable to meta-analysis. Thus, the quality of life results were not pooled. Data were pooled for the other primary outcome (improvement or cure) but there was a sufficient number of studies only for comparing 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 (relative risk, 0.75; 95% CI, 0.66 to 0.86). Reviewers noted 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; relative risk, 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 (mean difference, -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 below and in Tables 2 to 6. Other RCTs comparing the efficacy of PFMT alone with PFMT with biofeedback have been published.[13,14,15,16,] 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.

Weinstein et al (2022 and 2023) compared PFMT alone to PFMT with an intravaginal, motion-based therapeutic device incorporating intravaginal biofeedback with a smartphone app (Ieva® Pelvic Health System) in women with stress-induced or mixed urinary incontinence.[17,][18,] A total of 363 women were randomized and Urogenital Distress Inventory (UDI-6) score at 8 weeks was the primary outcome.[17,] The study was conducted virtually, and the patients received instructions to complete the 2.5 minute program 3 times daily for 8 weeks. Both groups had improved UDI-6 scores from baseline to week 8 with final scores of 42.8 (standard deviation [SD], 19.3) in the control group compared with 36.3 (SD, 20.8) in the intervention group. The mean change from baseline was 18.8 in the intervention group and 14.7 in the control group (p<.01). After 8 weeks, patients used the device at their own discretion with follow-up collected at 6 and 12 months.[18,] A total of 286 patients returned 6 and 12 month data (n=151 in the control group and n=135 in the intervention group). Mean between-group differences in UDI-6 scores were 5.4 (95% CI, 0.7 to 10.1; p=.03) at 6 months and 6.8 (95% CI, 1.7 to 11.9; p=.01) at 12 months. Although statistically significant, between-group differences in UDI-6 scores were numerically small and the scale lacks an established minimally clinically important difference.

Hagen et al (2020) conducted a multicenter RCT in 600 women with stress or mixed urinary incontinence.[19,] 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.[20,] They were randomized to intensive PFMT (n=79), PFMT using vaginal cones as a source of feedback (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 reduction in voiding frequency; there were no statistically significant differences in outcomes among the 3 groups. For example, the 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=.2).

Burgio et al (2002) reported on the 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 received behavioral training along with digital palpation instruction (no biofeedback) and 4 office visits in 8 weeks; (2) 73 patients received biofeedback-assisted behavioral training and 4 office visits in 8 weeks; and (3) 75 patients 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=.23). In addition, quality of life outcomes were similar in the 3 groups.

Table 2. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Weinstein et al (2022 and 2023)[17,18,]	US	NA*	2020-2021	Women ≥18 years of age with stress or stress-dominant mixed incontinence	PFMT with biofeedback (n=143)	PFMT alone (n=156)
Hagen et al (2020)[19,]	Scotland, England	23	2014-2016	Women ≥18 years of age with stress or mixed incontinence	PFMT with biofeedback (n=300)	PFMT alone (n=300)
Williams et al (2006)[20,]	UK	2	1998-2001	Women ≥40 years of age with stress or mixed incontinence	PFMT with vaginal cone for feedback (n=80)	PFMT alone (n=79) Behavioral training (n=79)
Burgio et al (2002)[2,]	US	1	1995-2001	Women ≥55 years of age with urge incontinence ≥2 times weekly for ≥3 months	Biofeedback with behavioral training (n=73)	Behavioral training without biofeedback (n=74) Self-administered behavioral treatment (n=75)

NA: not applicable; PFMT: pelvic floor muscle training; RCT: randomized controlled trial.
*Study was entirely conducted virtually.

Table 3. Summary of Key RCT Results

Study	UDI-6 at 8 Weeks (mean, SD)	SUI Episodes in 3-Day Diary at 8 Weeks (median, IQR)	UDI-6 Change at 6 Months (mean, SD)	UDI-6 change at 12 Months (mean, SD)
Weinstein et al (2022 and 2023)[17,18,]	N=299	N=299	N=286	N=286
PFMT with biofeedback	18.8 (15)	1 (0-3)	-20.2 (20.9)	-22.7 (23.3)
PFMT alone	14.7 (12.2)	2 (1-4)	-14.8 (19.5)	-15.9 (20.3)
Mean difference (95% CI); p-value	4.1 (1 to 7.2); p=.01	NR; p=.005	5.4 (0.7 to 10.1); p=.03	6.8 (1.7 to 11.9); p=.01
	ICIQ-UI-SF (mean, SD)	*Cure at 24 months (n, %)*	*Improvement at 24 months (n, %)*	
Hagen et al (2020)[19,]	N=460	N=460	N=460	
PFMT with biofeedback	8.2 (5.1)	18 (7.9%)	135 (60%)	
PFMT alone	8.5 (4.9)	20 (8.4%)	147 (62.6%)	
Effect size/OR(95% CI); p-value	-0.09 (-0.92 to 0.75); p=.84	0.90 (0.46 to 1.78); NR	0.89 (0.61 to 1.32); NR	
	Incontinence Episodes/ 24 h (change from baseline)	*Nocturnal Voids/night (change from baseline)*		
Williams et al (2006)[20,]	N=238	N=238		
PFMT with feedback	-0.28	-0.10		
PFMT alone	-1.03	-0.02		
Behavioral training	-0.59	0.03		
Risk difference	PFMT plus feedback vs PFMT: -0.75 (-1.65 to 0.16)	PFMT plus feedback vs PFMT: 0.79 (-0.12 to 0.28)		
	Reduction of IncontinenceEpisodes (%, SD)	*Patient Satisfaction (% completely satisfied)*		
Burgio et al (2002)[2,]	N=222	N=222		
Behavior with biofeedback	63.1% (42.7%)	75%		
Behavior without biofeedback	69.4% (32.7%)	85.5%		
Self-administered behavior training	58.6% (38.8%)	55.7%		
Effect size; p-value	NR; p=.23 amongst the 3 groups	NR; p=.001 amongst the 3 groups		

CI: confidence interval; HR: hazard ratio; ICIQ-UI-SF: International Consultation on Incontinence Questionnaire on Urinary Incontinence Short Form; NR: not reported; OR: odds ratio; PFMT: pelvic floor muscle training; RCT: randomized controlled trial; SD: standard deviation; SUI: stress urinary incontinence; UDI-6: Urogenital Distress Inventory, Short Form.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Weinstein et al (2022 and 2023)[17,18,]					
Hagen et al (2020)[19,]					3. Primary outcomes reported at 24 months, but treatment was complete by 16 weeks

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Williams et al (2006)[20],	4. Conducted solely in the UK				1, 2. Total of 12 weeks
Burgio et al (2002)[2],	4. Single-center; largely white; elderly			7. UDI-6 lacks established MCID	1, 2. Last follow-up at 10 weeks

MCID: minimally clinically important difference; UDI-6: Urogenital Distress Inventory, Short Form.
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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Weinstein et al (2022 and 2023)[17,18],		1. Participants not blinded				
Hagen et al (2020)[19],						
Williams et al (2006)[20],		1. Blinding not reported				
Burgio et al (2002)[2],		1. Blinding not reported		1. High rates of attrition in each group (9.3% to 15.1%)		3, 4. CI 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; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[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); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[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; 5. Other.

Section Summary: Women With Urinary Incontinence

Numerous RCTs and several systematic reviews have evaluated biofeedback as a treatment for 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). There is a lack of consistent evidence from well-designed trials to suggest that biofeedback is an effective treatment for urinary incontinence.

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

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 8 weeks).[21,]

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

Hsu et al (2016) published a systematic review of PFMT with biofeedback in men who had had a radical prostatectomy.[22,] Thirteen trials met reviewers' inclusion criteria. However, on inspection, not all trials included a biofeedback intervention, and other trials did not compare PFMT alone with PFMT plus biofeedback. Thus, conclusions about the added efficacy of biofeedback could not be determined from the results of this meta-analysis.

A Cochrane review by Johnson et al (2023) assessed conservative treatments for post-prostatectomy urinary incontinence.[23,] Reviewers included a comparison of PFMT (with or without biofeedback) and sham, verbal/written instructions, or no treatment. The authors did not evaluate the potential incremental 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.[24,] 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.[21,] 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; they were assessed at 6 and 12 months. The primary efficacy outcome was a 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-week treatment. In an intention-to-treat analysis of the primary outcome, the mean reduction in incontinent episodes was 55% (28 to 13 episodes per week) in the behavioral therapy group, 51% (26 to 12 episodes per week) in the behavior-plus group, and 24% (25 to 20 episodes per week) in the control group. The overall difference between groups was statistically significant (p=.001), but the behavior plus intervention did not result in a significantly better outcome than behavioral therapy alone. Findings were similar to 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 vs. 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, and have not consistently reported significantly improved outcomes with biofeedback added to the intervention. The timing and delivery of the intervention were not well-defined. Systematic reviews have not pooled study findings.

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

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 2 to 4 weeks before the procedure and continuing after; follow-up 3 to 12 months).[25,26,27,28,]

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

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.[25,] 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=.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.[26,] 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=.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=.005).

A trial by Wille et al (2003) randomized 139 men prior to radical prostatectomy to 1 of 3 groups.[27,] 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=.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=.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.[28,] 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% (48/40) in the control group.
Tables 6 and 7 more fully summarize key trial characteristics and results of these trials.

Table 6. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Oh et al (2020)[25,]	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)[26,]	Italy	1	2009-2010	38 patients who underwent standard open retropubic radical	Biofeedback (using anal probe [PelveenCare]) after	Verbal and written instructions on PFMT to be performed at home (n=16)

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
				prostatectomy for prostate cancer	catheter removal and PFMT (n=16)	
Wille et al (2003)[27,]	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)[28,]	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.

Table 7. Summary of Key Randomized Controlled Trial Results

Study (Year)	Final N	Continence		Average 24-hour urine loss
Oh et al (2020)[25,]		*Loss of 0 g of urine on a 24-h 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 g (month 3)
p value		.649		.028 (month 1),.744 (month 2),.415 (month 3)
Tienforti et al (2012)[26,]		*ICIQ-UI score of 0*		
Biofeedback + PFMT	16	6/16 (month 1), 8/16 (month 2), 10/16 (month 3)		NR
PFMT	16	0/16 (month 1), 1/16 (month 2), 1/16 (month 3)		NR
p value		.02 (month 1),.01 (month 2),.002 (month 3)		NR
Wille et al (2003)[27,]		*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		.815 (immediate postsurgical),.524 (12 months)	.822 (immediate postsurgical),.236 (12 months)	NR
Bales et al (2000)[28,]		*Use of 1 or less pad per day*		
Biofeedback + PFMT	47	44/47 (94%) (6 months)		NR
PFMT	50	48/50 (96%) (6 months)		NR
p value		.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 8 and 9 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.[26,]

Table 8. Study Relevance Limitations

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
Oh et al (2020)[25,]				1. Key health outcomes not addressed; 3. Incomplete reporting of harms	
Tienforti et al (2012)[26,]			3. Delivery not similar intensity as intervention		
Wille et al (2003)[27,]				1. Key health outcomes not addressed; 3. Incomplete reporting of harms	
Bales et al (2000)[28,]			3. Delivery not similar intensity as intervention	1. Key health outcomes not addressed; 3. Incomplete 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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 9. Study Design and Conduct Limitations

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Oh et al (2020)[25,]		1. Not blinded to treatment assignment; 2. Not blinded outcome assessment				
Tienforti et al (2012)[26,]		1. Not blinded to treatment assignment				
Wille et al (2003)[27,]	3. Allocation concealment unclear	1. Not blinded to treatment assignment; 2. Not blinded outcome assessment			1. Power calculations not reported	

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Bales et al (2000)[28,]	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; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[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); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[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; 5. Other.

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. The timing and delivery of the intervention were not well-defined.

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.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009 Input

In response to requests, input was received from 4 physician specialty societies and 2 academic medical centers while this policy was under review in 2009. Clinical input varied. Several reviewers commented on the lack of data (e.g., those who cannot do pelvic exercises) as well as the inability to separate in the available literature the contribution of biofeedback to overall outcomes in many studies.

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 US professional society, an international society with US 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 Obstetricians and Gynecologists and the American Urogynecologic Society

The American College of Obstetricians and Gynecologists and the American Urogynecologic Society issued a practice bulletin (issued 2015; reaffirmed 2022) on urinary incontinence in women.[29,] The

practice bulletin states, "Pelvic muscle exercises may be used alone or augmented with bladder training, biofeedback, or electrical stimulation."

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 pelvic floor muscle training 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."[30,]A 2023 update to these guidelines which focused on surgical treatment of stress urinary incontinence include a recommendation for pelvic floor exercises with or without biofeedback as a nonsurgical option.[31,]

The 2024 American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction guideline on overactive bladder includes biofeedback as an example of non-invasive therapies.[32,] Although they make no specific recommendations for biofeedback, they state, "Clinicians may offer select non-invasive therapies to all patients with OAB." However, they caution, "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."

The American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction guideline (2019; amended 2024) on treating incontinence after prostate treatment states that the randomized controlled trials that were assessed differed on the regimen of pelvic floor muscle training, with some studies including biofeedback or electrical stimulation.[33,] Guideline Statement 16 recommends pelvic floor muscle exercises or pelvic floor muscle training after radical prostatectomy, but biofeedback is not mentioned as part of the treatment.

National Institute for Health and Care Excellence

In 2019, the NICE updated its guidance on the management of urinary incontinence in women.[34,] 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".

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In 2001, the Centers for Medicare & Medicaid issued a national coverage determination.[35,] 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 August 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
	90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
	90901	Biofeedback training by any modality
	90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
	90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)
HCPCS	E0746	Electromyography (EMG), biofeedback device

Policy History

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

Effective Date	Action
01/11/2008	New Policy Adoption of BCBSA MPP 7.01.106. Content enhanced by merging BSC policies Urinary Incontinence Treatment and Endoscopic Injections for Urinary Incontinence, Codes updated. Policy title change. Prior policy title Urinary Incontinence Treatment.
03/01/2009	Coding Update
04/02/2010	Policy Revision with position change
04/14/2010	Coding Update
10/29/2010	Coding Update
01/21/2011	Coding Update
01/12/2012	Coding Update
07/03/2013	Policy revision with position change
02/27/2015	Policy title change from Urinary Incontinence Outpatient Treatment BCBSA Medical Policy adoption Policy revision with position change
01/01/2017	Policy revision without position change
03/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
10/01/2018	Policy revision without position change
10/01/2019	Policy revision without position change
03/01/2020	Coding Update
10/01/2020	Annual review. No change to policy statement. Literature review updated.
10/01/2021	Annual review. No change to policy statement. Literature review updated.
10/01/2022	Annual review. No change to policy statement. Literature review updated.
10/01/2023	Annual review. No change to policy statement. Policy guidelines updated.
12/01/2024	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are 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 or 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.

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

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California 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 contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Biofeedback as a Treatment of Urinary Incontinence in Adults 2.01.27 **Policy Statement:** I. Biofeedback in the outpatient setting is considered **investigational** as a treatment of urinary incontinence in adults. II. Unsupervised home use of biofeedback for treatment of urinary incontinence is considered **investigational**.	**Biofeedback as a Treatment of Urinary Incontinence in Adults 2.01.27** **Policy Statement:** I. Biofeedback in the outpatient setting is considered **investigational** as a treatment of urinary incontinence in adults. II. Unsupervised home use of biofeedback for treatment of urinary incontinence is considered **investigational**.