



Kansas City

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# Biofeedback as a Treatment of Urinary Incontinence in Adults

**Policy Number:** 2.01.27

**Last Review:** 10/2018

**Origination:** 7/2008

**Next Review:** 10/2019

## Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for biofeedback as a treatment of urinary incontinence. This is considered investigational.

Biofeedback and biofeedback devices are specifically excluded under many benefit plans. In addition, biofeedback and biofeedback devices are considered behavioral training and education/training in nature, and such services are also specifically excluded under many benefit plans.

## When Policy Topic is covered

Not Applicable

## When Policy Topic is not covered

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

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

## Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>▪ With urinary incontinence (women)</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>▪ Biofeedback with pelvic floor muscle training</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>▪ Pelvic floor muscle training without biofeedback</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>▪ Symptoms</li> <li>▪ Functional outcomes</li> <li>▪ Quality of life</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>▪ With post-prostatectomy urinary incontinence</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>▪ Biofeedback with pelvic floor muscle training</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>▪ Pelvic floor muscle training without biofeedback</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>▪ Symptoms</li> <li>▪ Functional outcomes</li> <li>▪ Quality of life</li> </ul>

<b>Individuals:</b> <ul style="list-style-type: none"> <li>▪ Who are scheduled for radical prostatectomy</li> </ul>	<b>Interventions of interest are:</b> <ul style="list-style-type: none"> <li>▪ Biofeedback with pelvic floor muscle training</li> </ul>	<b>Comparators of interest are:</b> <ul style="list-style-type: none"> <li>▪ Pelvic floor muscle training without biofeedback</li> </ul>	<b>Relevant outcomes include:</b> <ul style="list-style-type: none"> <li>▪ Symptoms</li> <li>▪ Functional outcomes</li> <li>▪ Quality of life</li> </ul>
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Biofeedback is a technique to teach patients 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.

For individuals who have urinary incontinence (women) who receive biofeedback with PFMT, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. 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. There is a lack of consistent evidence from well-designed trials that biofeedback effectively treats urinary incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have post-prostatectomy urinary incontinence or who are scheduled for radical prostatectomy who receive biofeedback with PFMT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Several RCTs have compared PFMT with or without biofeedback in men undergoing radical prostatectomy, and in men with post-prostatectomy urinary incontinence. These trials had mixed findings, but did not consistently report significantly improved outcomes when biofeedback was added to the intervention. The timing and delivery of the intervention were not well-defined. Additional well-designed trials are needed that demonstrate the superiority of biofeedback with PFMT over PFMT alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Background**

Urinary Incontinence is a common condition defined as an involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects quality of life and treatment decisions. The types of urinary incontinence include stress, urge, overflow, functional, and postprostatectomy incontinence.

Nonsurgical treatment options may include pharmacologic treatment, pelvic muscle exercises, bladder training exercises, electrical stimulation, and neuromodulation.

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, nonarousing 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 PFMT, 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. There are several proposed methods of biofeedback that may be employed for the treatment of urinary incontinence, including 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 individual attempts to control, and the information that is fed back to the individual. 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).

### **Regulatory Status**

A variety of biofeedback devices are cleared for marketing through the Food and Drug Administration's (FDA) 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".

### **Rationale**

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This evidence review was created in July 1997 and was updated regularly with searches of the MEDLINE database. The most recent literature update was performed through June 7, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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.

Several methodologic difficulties arise in assessing biofeedback.<sup>1</sup> 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 (eg, relaxation or behavioral therapy alone). In addition, although research has shown that feedback on physiologic processes has enhanced patients' 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 the 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 evidence review is: Does the use of biofeedback with PFMT improve the net health outcome in women with urinary incontinence?

The following PICOTS were used to select literature to inform this review.

### ***Patients***

The relevant population of interest is women with 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 discontinuation (eg, incontinence episodes) and functional improvement.

### ***Timing***

Biofeedback training is designed to guide and enhance PFMT.

### ***Setting***

Biofeedback is provided in an outpatient setting by a therapist.

### **Systematic Reviews**

Moroni et al (2016) published a systematic review of 37 RCTs evaluating conservative treatment of stress urinary incontinence in women.<sup>2</sup> 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, 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 a single study. Results on other outcomes (eg, 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 (total N=542 patients) comparing PFMT plus biofeedback with PFMT alone.<sup>3</sup> 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.<sup>4</sup> 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 four of them reported data in a form amenable to meta-analysis. Thus, 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 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; 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.

As implied in the description of the Cochrane review, studies evaluating biofeedback for treating urinary incontinence in women have used various combinations of interventions and comparator interventions. Selected larger RCTs that compared PFMT with and without biofeedback (to isolate the effect of biofeedback and published as full articles are described next).

### **Randomized Controlled Trials**

Burgio et al (2002) reported on the findings of an RCT with 222 women who had urge or mixed incontinence.<sup>5</sup> 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 ( $p=0.23$ ). In addition, quality of life outcomes were similar in the 3 groups.

Williams et al (2006) published a study that included 238 women who had failed a primary behavioral therapy (eg, advice on fluid intake, bladder reeducation, weight loss) for 3 months.<sup>6</sup> 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 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 ( $p=0.2$ ).

Other RCTs comparing the efficacy of PFMT alone with PFMT with biofeedback have been published.<sup>7,8</sup> They tended not to find statistically significant differences in outcomes between interventions; however, sample sizes were small (ie, <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 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 (eg, improvement or cure, urine volume) but not others (eg, 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 or 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 evidence review is: Does the use of biofeedback with PFMT improve the net health outcome in men with post-prostatectomy urinary incontinence or men scheduled for radical prostatectomy?

The following PICOTS were used to select literature to inform this review.

### ***Patients***

The relevant populations of interest are men with post-prostatectomy urinary incontinence and 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 reduction and functional outcomes.

### ***Timing***

Biofeedback training is designed to guide and enhance PFMT.

### ***Setting***

Biofeedback is provided in an outpatient setting by a therapist.

## **Post-Prostatectomy Urinary Incontinence**

### ***Systematic Reviews***

A Cochrane review by Anderson et al (2015) assessed conservative treatments for post-prostatectomy urinary incontinence.<sup>9</sup> Reviewers included a comparison of PFMT (with or without biofeedback) and sham or no treatment. They did not evaluate the potential incremental value of biofeedback (ie, by comparing PFMT with biofeedback and PFMT without biofeedback).

Hsu et al (2016) published a systematic review of PFMT with biofeedback in men who had had radical prostatectomy.<sup>10</sup> 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.

Previously, MacDonald et al (2007) conducted a systematic review of PFMT to improve urinary incontinence after radical prostatectomy.<sup>11</sup> 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.<sup>12</sup> 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% (28-13 episodes per week) in the behavioral therapy group, 51% (26-12 episodes per week) in the behavior-plus group, and 24% (25-20 episodes per 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 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***

RCTs have evaluated the efficacy of biofeedback with PFMT for treatment of prostatectomy-related urinary incontinence compared with PFMT without biofeedback. These trials had mixed findings, 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**

### ***Randomized Controlled Trials***

A few trials have evaluated the use of pre- or perioperative biofeedback for patients undergoing radical prostatectomy for prevention of postoperative urinary incontinence.

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.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> 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; incidence of urinary incontinence was 94% (44/47) in the PFMT plus biofeedback group and 96% (94/40) in the control group.

### **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 reported poor outcomes with biofeedback added to the intervention. The timing and delivery of the intervention were not well-defined.

### **Summary of Evidence**

For individuals who have urinary incontinence (women) who receive biofeedback with PFMT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. 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. There is a lack of consistent evidence from well-designed trials that biofeedback effectively treats urinary incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have post-prostatectomy urinary incontinence or who are scheduled for radical prostatectomy who receive biofeedback with PFMT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Several RCTs have compared PFMT with or without biofeedback in men undergoing radical prostatectomy, and in men with post-prostatectomy urinary incontinence. These trials had mixed findings but did not consistently report significantly improved outcomes when biofeedback was added to the intervention. The timing and delivery of the intervention were

not well-defined. Additional well-designed trials are needed that demonstrate the superiority of biofeedback with PFMT over PFMT alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Supplemental Information**

### **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.

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 (eg, 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**

#### **American Urological Association et al**

In their 2017 guidelines on treatment of stress urinary incontinence in women, the American Urological Association and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction 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."<sup>16</sup>

#### **American College of Physicians**

The American College of Physicians (2014) published clinical guidelines on the nonsurgical management of urinary incontinence in women.<sup>17</sup> The guidelines were based on literature published through December 2013. The College concluded that low-quality evidence showed pelvic floor muscle training (PFMT) with biofeedback using a vaginal electromyography probe increased continent compared with no active treatment and that high-quality evidence showed this combination of treatments improved urinary incontinence symptoms compared with no active treatment. The guidelines did not compare PFMT alone and PFMT plus biofeedback.

#### **National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2015) updated its guidance on the management of urinary incontinence in women.<sup>18</sup> 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”.

### **Canadian Urological Association**

The Canadian Urological Association (2012) issued guidelines on the treatment of adult urinary incontinence.<sup>19</sup> The guidelines drew the following conclusions on the use of biofeedback for post-prostatectomy incontinence and stress incontinence, respectively:

“Preoperative biofeedback-assisted behavioural training can shorten the time to regain continence postoperatively and reduce the prevalence of severe incontinence 6 months after the procedure (level of evidence 2, grade B)... Postoperative ... biofeedback does not appear to improve continence outcomes compared with PFMT (level of evidence 2, grade B).

“The benefit of biofeedback is unknown (grade B).”

### **National Institutes of Health**

The National Institutes of Health (2007) convened a consensus development conference on prevention of fecal and urinary incontinence; it subsequently released a statement that addressing PFMT and biofeedback<sup>20</sup>:

“Pelvic floor muscle training and biofeedback are effective in preventing and reversing some pregnancy-related fecal and urinary incontinence for the first year after delivery. There is insufficient research on the sustained long-term benefits of pelvic floor muscle training or biofeedback on preventing fecal or urinary incontinence.”

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

The Centers for Medicare & Medicaid issued a national coverage determination in 2001.<sup>21</sup> 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](http://ClinicalTrials.gov) in July 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

#### References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Biofeedback. TEC Assessments. 1995;Volume 10:Tab 25.
2. Moroni RM, Magnani PS, Haddad JM, et al. Conservative treatment of stress urinary incontinence: a systematic review with meta-analysis of randomized controlled trials. *Rev Bras Ginecol Obstet.* Feb 2016;38(2):97-111. PMID 26883864
3. Shamliyan T, Wyman J, Kane RL, et al. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness. Comparative Effectiveness Review No. 36. Rockville, MD: Agency for Healthcare Research and Quality; 2012.
4. Herderschee R, Hay-Smith EJ, Herbison GP, et al. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. *Cochrane Database Syst Rev.* Jul 6 2011(7):CD009252. PMID 21735442
5. Burgio KL, Goode PS, Locher JL, et al. Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: a randomized controlled trial. *JAMA.* Nov 13 2002;288(18):2293-2299. PMID 12425706
6. Williams KS, Assassa RP, Gillies CL, et al. A randomized controlled trial of the effectiveness of pelvic floor therapies for urodynamic stress and mixed incontinence. *BJU Int.* Nov 2006;98(5):1043-1050. PMID 17034605
7. Hirakawa T, Suzuki S, Kato K, et al. Randomized controlled trial of pelvic floor muscle training with or without biofeedback for urinary incontinence. *Int Urogynecol J.* Aug 2013;24(8):1347-1354. PMID 23306768
8. Pereira VS, de Melo MV, Correia GN, et al. Vaginal cone for postmenopausal women with stress urinary incontinence: randomized, controlled trial. *Climacteric.* Feb 2012;15(1):45-51. PMID 22066898
9. Anderson CA, Omar MI, Campbell SE, et al. Conservative management for postprostatectomy urinary incontinence. *Cochrane Database Syst Rev.* Jan 20 2015;1:CD001843. PMID 25602133
10. Hsu LF, Liao YM, Lai FC, et al. Beneficial effects of biofeedback-assisted pelvic floor muscle training in patients with urinary incontinence after radical prostatectomy: A systematic review and metaanalysis. *Int J Nurs Stud.* Aug 2016;60:99-111. PMID 27297372
11. MacDonald R, Fink HA, Huckabay C, et al. Pelvic floor muscle training to improve urinary incontinence after radical prostatectomy: a systematic review of effectiveness. *BJU Int.* Jul 2007;100(1):76-81. PMID 17433028
12. Goode PS, Burgio KL, Johnson TM, 2nd, et al. Behavioral therapy with or without biofeedback and pelvic floor electrical stimulation for persistent postprostatectomy incontinence: a randomized controlled trial. *JAMA.* Jan 12 2011;305(2):151-159. PMID 21224456
13. Tienforti D, Sacco E, Marangi F, et al. Efficacy of an assisted low-intensity programme of perioperative pelvic floor muscle training in improving the recovery of continence after radical prostatectomy: a randomized controlled trial. *BJU Int.* Oct 2012;110(7):1004-1010. PMID 22332815
14. Wille S, Sobottka A, Heidenreich A, et al. Pelvic floor exercises, electrical stimulation and biofeedback after radical prostatectomy: results of a prospective randomized trial. *J Urol.* Aug 2003;170(2 Pt 1):490-493. PMID 12853806

15. Bales GT, Gerber GS, Minor TX, et al. Effect of preoperative biofeedback/pelvic floor training on continence in men undergoing radical prostatectomy. *Urology*. Oct 1 2000;56(4):627-630. PMID 11018619
16. Kobashi KC, Albo ME, Dmochowski RR, et al. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. 2017. Accessed July 27, 2018.
17. Qaseem A, Dallas P, Forcica MA, et al. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Sep 16 2014;161(6):429-440. PMID 25222388
18. National Institute for Health and Care Excellence (NICE). Urinary incontinence in women: management [CG171]. 2015; <https://www.nice.org.uk/Guidance/CG171>. Accessed July 12, 2018.
19. Bettez M, Tu le M, Carlson K, et al. 2012 update: guidelines for adult urinary incontinence collaborative consensus document for the Canadian Urological Association. *Can Urol Assoc J*. Oct 2012;6(5):354-363. PMID 23093627
20. Shamilyan T, Wyman J, Bliss DZ, et al. Prevention of urinary and fecal incontinence in adults. Evidence Reports/Technology Assessments No. 161. Rockville, MD Agency for Healthcare Research and Quality; 2007.
21. Centers for Medicare & Medicaid Services. National coverage decision (NCD) for biofeedback therapy for the treatment of urinary incontinence (30.1.1). 2001; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=42&ncdver=1&CoverageSelection=National&Keyword=Biofeedback+Urinary+Incontinence&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAAAAA%3d%3d&>. Accessed July 12, 2018.

## **Billing Coding/Physician Documentation Information**

- 90875** Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes
- 90876** Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); approximately 45-50 minutes
- 90901** Biofeedback training by any modality
- 90911** Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry
- E0746** Electromyography (EMG), biofeedback device

## **Policy Implementation/Update Information**

- 7/1/08 New policy; considered investigational.
- 7/1/09 No policy statement changes.
- 7/1/10 Unsupervised home use of biofeedback for treatment of urinary incontinence included as investigational.
- 7/1/11 Policy statement revised; "outpatient setting" added to first policy statement.
- 7/1/12 No policy statement changes.
- 7/1/13 No policy statement changes.
- 10/1/13 No policy statement changes.
- 10/1/14 No policy statement changes.
- 10/1/15 No policy statement changes.
- 10/1/16 No policy statement changes.

10/1/17 No policy statement changes.

10/1/18 No policy statement changes.

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