Biofeedback as a Treatment of Urinary Incontinence in Adults

Policy Number: 2.01.27  Last Review: 10/2017
Origination: 7/2008  Next Review: 10/2018

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

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<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<tr>
<td>With urinary incontinence (women)</td>
<td>Biofeedback with pelvic floor muscle training</td>
<td>Pelvic floor muscle training without biofeedback</td>
<td>Symptoms</td>
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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 though 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**
This evidence review was originally created in July 1997 and was updated regularly with searches of the MEDLINE database. Most recently, the literature was reviewed through November 15, 2016. Following is a summary of the key literature to date.

Several methodologic difficulties arise in assessing biofeedback.(1) For example, most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have effects separate from those due to
biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. For example, relaxation, attention, or suggestion may account for successful results that have been attributed to biofeedback. These effects are nonspecific therapeutic factors, some of which can be considered placebo effects. To demonstrate efficacy of biofeedback for treating incontinence, studies are needed to isolate the effect of biofeedback and demonstrate an improvement in health outcomes compared with other interventions (eg, relaxation or behavioral therapy alone). In addition, although studies in the 1990s found that feedback on physiologic processes provided patients with an enhanced ability to control these processes, evidence is needed on the relation between a patient’s ability to exert control over the targeted physiologic process and any health benefits of the intervention. The latter finding underscores the importance of seeking controlled studies showing whether use of biofeedback improves disease-related health outcomes, as opposed to physiologic, intermediate outcomes.

WOMEN WITH URINARY INCONTINENCE
A number of randomized controlled trials (RCTs) addressing biofeedback for urinary incontinence have been published, and there are several systematic reviews of RCTs.

Systematic Reviews
Most recently, in 2016, Moroni et al published a systematic review of 37 randomized controlled trials (RCTs) on conservative treatment of stress urinary incontinence in women.(2) Five trials were identified that compared pelvic floor muscle training (PFMT) plus biofeedback with biofeedback alone; the studies included a total of 250 women. A pooled analysis of 4 studies found significantly more urine loss as measured by a posttreatment pad test with PFMT alone than with PFMT plus biofeedback (mean difference [MD], 0.90; 95% confidence interval [CI], 0.71 to 1.10). Reviewers noted that the difference between groups was likely not clinically significant because there was only about a 1-gram difference. Moreover, the finding was largely due to the effect of 1 study. Results on other outcomes (eg, quality of life, number of incontinence episodes) could not be pooled due to imprecision of the estimates.

In 2012, an Agency for Healthcare Research and Quality comparative effectiveness review identified 6 RCTs (total N=542 patients) comparing PFMT plus biofeedback with PFMT alone.(3) A meta-analysis of these studies did not find a statistically significant difference between interventions in continence rates. When findings were pooled, the relative risk (RR) was 1.27 (95% CI, 0.88 to 1.85). The absolute risk difference was 0.08 (95% CI, -0.03 to 0.19).

A 2011 Cochrane systematic review of RCTs included studies on feedback or biofeedback in conjunction with PFMT for treating urinary incontinence in women.(4) 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 these 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 were a sufficient number of studies only for the comparison between PFMT with and without biofeedback. In a pooled analysis of 7 studies, there was a significant reduction in the proportion of women reporting “no improvement or cure” when biofeedback was added to muscle exercise (RR=0.75; 95% CI, 0.66 to 0.86). Reviewers noted that there may have been other differences between groups, such as more frequent contact with a health care professional or a greater number of treatment sessions, which might partially explain the difference between the improvement or cure rates in women who did or did not receive biofeedback. Moreover, when only the outcome “no cure” was examined, there was no significant difference between groups that did and did not receive biofeedback (5 studies; RR=0.92; 95% CI, 0.81 to 1.05). Among secondary outcomes, a pooled analysis of 7 trials did not find a significant difference in leakage episodes in a 24-hour period after treatment (MD = -0.01; 95% CI, -0.21 to 0.01). For the outcomes frequency and nocturia, data could not be combined but reviewers reported that the pattern was one of no difference between groups.

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

**Randomized Controlled Trials**

Burgio et al (2002) reported on findings of an RCT with 222 women who had urge or mixed incontinence.(5) Interventions in this 3-armed trial were as follows: (1) 74 patients who received behavioral training along with digital palpation instruction (no biofeedback) and 4 office visits in 8 weeks; (2) 73 patients who received biofeedback-assisted behavioral training and 4 office visits in 8 weeks; and (3) 75 patients who were given a self-help book with no office visits (control condition). Behavioral training in the 2 intervention groups included teaching pelvic floor exercises as well as skills and strategies for reducing incontinence. Patients in all groups kept bladder diaries through the 8-week treatment period. In an intention-to-treat analysis, the mean reduction in incontinence episodes was 69.4% in the behavioral training plus verbal feedback group, 63.1% in the behavioral training plus biofeedback group, and 58.6% in the control group. The 3 groups did not differ significantly from one another (p=0.23). In addition, quality-of-life outcomes were similar in the 3 groups.

In 2006, Williams et al published a U.K. study that included 238 women who had failed a primary behavioral therapy (eg, advice on fluid intake, bladder reeducation, weight loss) for 3 months.(6) They were randomized to intensive
PFMT (n=79), PFMT using vaginal cones (n=80), or continued behavioral therapy (n=79) for 3 months. Patients in all 3 groups were seen in the clinic every other week for 8 weeks and at 12 weeks. At 12 weeks, all 3 groups had moderate reductions in incontinence episodes and some improvement in voiding frequency; there were no statistically significant differences in outcomes among the 3 groups. For example, mean reduction in incontinence episodes over 24 hours was -1.03 in the PFMT group, -0.28 in the vaginal cone group, and -0.59 in the control group (p=0.2).

Several other RCTs comparing the efficacy of PFMT alone with PFMT with biofeedback were published in 2012 and 2013.(7,8) 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 may have been underpowered.

**Section Summary: Women With Urinary Incontinence**
Numerous RCTs have evaluated biofeedback as a treatment of urinary incontinence in women and there have been several systematic reviews. The methodology of the studies 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 of urinary incontinence.

**MEN WITH PROSTATECTOMY-RELATED URINARY INCONTINENCE**
Several RCTs evaluating biofeedback to treat prostatectomy-related urinary incontinence have been published. In addition, there have been several systematic reviews of these RCTs.

**Post-Prostatectomy Urinary Incontinence**

**Systematic Reviews**
In 2015, a Cochrane review assessed conservative treatments for post-prostatectomy urinary incontinence.(9) Reviewers included a comparison of PFMT (with or without biofeedback) and sham or no treatment. They did not evaluate the potential added value of biofeedback (ie, by comparing PFMT with biofeedback and PFMT without biofeedback).

In 2016, Hsu et al published a systematic review of PFMT with biofeedback in men who had radical prostatectomy.(10) Thirteen trials met reviewers’ inclusion criteria. However, on closer inspection, not all trials included a biofeedback intervention, and other trials did not compare PFMT alone to PFMT plus biofeedback. Thus, conclusions about the added efficacy of biofeedback cannot be determined from the results of this meta-analysis.
Previously, in 2007, MacDonald et al published a systematic review of PFMT to improve urinary incontinence after radical prostatectomy. 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**

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

**Planned Radical Prostatectomy**

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

In 2012, Tienforti et al in Italy reported on a RCT comparing biofeedback (sessions before and after surgery) in combination pelvic floor muscle exercises with a control intervention PFMT alone in patients undergoing radical prostatectomy. 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 2003 randomized trial by Wille et al randomized 139 men prior to radical prostatectomy to 1 of 3 groups.(14) 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).

In 2000, Bales et al 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 (15). 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, the incidence of urinary incontinence was 94% (44/47) in the PFMT plus biofeedback group and 96% (94/40) in the control group. The difference between groups was not statistically significant.

**Section Summary: Men With Prostatectomy-Related Urinary Incontinence**

RCTs have evaluated the efficacy of biofeedback with PFMT for prevention and/or treatment of prostatectomy-related urinary incontinence compared to PFMT without biofeedback. 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. Systematic reviews have not pooled study findings.

**SUMMARY OF EVIDENCE**

For individuals who have urinary incontinence (women) who receive biofeedback with pelvic floor muscle training (PFMT), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. 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 2014 guidelines on diagnosis and treatment of overactive bladder (OAB), the American Urological Association and Society of Urodynamics, Female Pelvic Medicine & Urogential Reconstruction did not make specific recommendations on biofeedback.(16) The guidelines included the statement: “Clinicians should offer behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as first line therapy to all patients with OAB”.

American College of Physicians
In 2014, the American College of Physicians (ACP) published clinical practice guidelines on nonsurgical management of urinary incontinence in women.(17) The guidelines were based on literature published through December 2013. ACP concluded that low-quality evidence showed pelvic floor muscle training (PFMT) with biofeedback using a vaginal electromyography probe increased continent compared to no active treatment and that high-quality evidence showed this combination of treatments improved urinary incontinence symptoms compared to no active treatment. The guidelines did not compare PFMT alone and PFMT plus biofeedback.
National Institute for Health and Clinical Excellence
In 2015, the National Institute for Health and Clinical Excellence updated its 2006 guidance on the management of urinary incontinence in women.(18) 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
In 2012, the Canadian Urological Association issued guidelines on treatment of adult urinary incontinence.(19) The guidelines made the following conclusions on the use of biofeedback:

Post-prostatectomy incontinence: “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).

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

National Institutes of Health
In 2007, the National Institutes of Health convened a consensus development conference on prevention of fecal and urinary incontinence; it subsequently released a statement that addressing PFMT and biofeedback20:

“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
A national coverage determination was published in 2001.(21) 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 November 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

References:


**Billing Coding/Physician Documentation Information**

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<th>Description</th>
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<td>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</td>
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<td>Electromyography (EMG), biofeedback device</td>
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**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.
Biofeedback as a Treatment of Urinary Incontinence in Adults 2.01.27

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.

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