Title: Biofeedback

Description/Background

Biofeedback is a technique intended to teach patients self-regulation of certain unconscious or involuntary physiologic processes. The technique involves the feedback of a variety of types of information not usually 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 a specific way.

Biofeedback has been proposed as a treatment for a variety of diseases and disorders including, but not limited to, anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia. The type of feedback used in an intervention (eg, visual, auditory) depends on the nature of the disease or disorder under treatment.

Regulatory Status

A large number of biofeedback devices have been cleared through the U.S. Food and Drug Administration’s 510(k) process.

Medical Policy Statement

The safety and effectiveness of biofeedback have been established. It may be considered a useful therapeutic option for patients meeting selection criteria.
Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:
• The treatment of stress and/or urge urinary incontinence in cognitively intact adults who have failed a documented trial of pelvic muscle exercise (PME) training. A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.
• For children with daytime urinary dysfunction when the child meets the following criteria:
  o Ages four years or older
  o Neurologic, anatomic, infectious or functional causes have been ruled out
  o Able to comprehend and follow verbal instructions
• Biofeedback for fecal incontinence or constipation is indicated for those who are motivated, and mentally capable. Patients must have some degree of rectal sensation and be able to contract the external anal sphincter.
• Biofeedback for migraine and tension-type headache when used as part of the overall treatment plan.

Exclusions:
• Cluster headaches
• Chronic pain
• Hypertension
• Stroke
• All other conditions not noted in the inclusionary guidelines

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:
  90901 90911

Other codes (investigational, not medically necessary, etc.):
  N/A

Rationale

Urinary Incontinence

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 research has shown that feedback on physiologic processes has enhanced patients’ ability to control over the targeted physiologic process and any health benefits of the intervention. The latter finding underscores the importance of seeking controlled studies showing whether use of biofeedback improves disease-related health outcomes, as opposed to physiologic, intermediate outcomes.

WOMEN WITH URINARY INCONTINENCE
Clinical Context and Therapy Purpose
The purpose of biofeedback with pelvic floor muscle training (PFMT) in women who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement in 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

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 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. 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. 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 healthcare 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 implied 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 (to isolate the effect of biofeedback and 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. 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.
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. 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).

Other RCTs comparing the efficacy of PFMT alone with PFMT with biofeedback have been published. 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. 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).

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.9 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 radical prostatectomy.10 Thirteen trials met reviewers’ inclusion criteria. However, on inspection, not all trials included a biofeedback intervention, and other trials did not compare PFMT alone to PFMT plus biofeedback. Thus, conclusions about the added efficacy of biofeedback cannot be determined from the results of this meta-analysis.

Previously, MacDonald et al (2007) published a systematic review of PFMT to improve urinary incontinence after radical prostatectomy.11 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 a RCT evaluating biofeedback and PFMT in 208 men with urinary incontinence persisting at least 1 year after radical prostatectomy.12 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
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**

**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 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 trial by Wille et al (2003) randomized 139 men prior to radical prostatectomy to 1 of 3 groups. 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. 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% (498/40) 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. Systematic reviews have not pooled study findings.

**Summary of Evidence: Urinary Incontinence**

The evidence for treatment of urinary incontinence (women) who receive biofeedback with pelvic floor muscle training (PFMT) 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.

The evidence for treatment of individuals with post-prostatectomy urinary incontinence or those 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.

There is lack of data evaluating biofeedback for individuals who are unable to undergo PFMT or who fail treatment with PFMT. Studies on biofeedback demonstrate improvement in symptoms of urinary incontinence and results are fairly comparable to those achieved with PFMT, therefore the addition of biofeedback to the therapeutic regime may be useful for in patients who fail other treatments.

**Daytime Urinary Dysfunction in Children**

A synthesis of the evidence on management of bladder dysfunction in children (UpToDate 2018) states, "biofeedback is reserved for children with bladder and sphincter dyssynergia that is contributing to persistent daytime incontinence despite an adequate trial of conservative therapy and/or pharmacotherapy." The publication notes that data on effective treatment of bladder dysfunction in children is limited due to flaws in study design. However, "several observational studies in children report that biofeedback therapy appears to reduce symptoms associated with bladder dysfunction and decrease postvoid residual volumes."¹

**Fecal Incontinence**

**Adults**

**Systematic Reviews**

Numerous RCTs and several systematic reviews of RCTs on biofeedback treatment for fecal incontinence in adults have been published. In 2009, Enck et al identified 11 RCTs evaluating the efficacy of biofeedback therapy for fecal incontinence in adult populations.¹ Two RCTs were excluded, one because of the small sample size and the other because it did not include an appropriate control group. The remaining 9 studies comprised 5 comparisons of different biofeedback modalities and 6 comparisons of electromyographic (EMG) biofeedback versus other types of therapy, mainly pelvic floor exercises. (Two studies had multiple treatment groups and were included in both categories.) The total number of patients included in the 9 studies was 540; sample sizes of individual studies ranged from 18 to 171 patients. A meta-analysis of 5 studies did not find a significant difference in the efficacy of different types of biofeedback (pooled odds ratio [OR], 1.23; 95% confidence interval [CI], 0.74 to 2.20; p=0.38). Similarly, a meta-analysis of studies comparing biofeedback with other therapies did not find a significant difference in efficacy (pooled OR=1.19; 95% CI, 0.69 to 2.05). The outcome measure used in the analysis was not specified and appeared to vary from study to study.

Other systematic reviews have addressed biofeedback alone and in combination with other interventions. A 2013 systematic review by Vonthein et al identified 13 RCTs on biofeedback,
electrical stimulation, or their combination for treatment of fecal incontinence. Ten trials compared biofeedback with an alternative treatment; some of the biofeedback interventions involved other components such as sensory training and pelvic floor exercises. A meta-analysis of studies comparing biofeedback with a control intervention significantly favored biofeedback (relative risk, 2.12; 95% CI, 1.42 to 3.16). Reviewers did not isolate the effect of biofeedback in multicomponent interventions that included pelvic floor exercise or other treatments. A 2012 Cochrane review identified 21 RCTs evaluating biofeedback and/or sphincter exercises for treating fecal incontinence in adults. Most studies used multifaceted interventions (eg, biofeedback, education, sphincter exercise). Additionally, a wide variety of control interventions were used. Three trials compared biofeedback plus sphincter exercises with sphincter exercises alone, and 1 trial compared biofeedback plus 1 type of exercise with biofeedback plus another type of exercise. Reviewers did not pool study findings due to heterogeneity among trials.

**Randomized Controlled Trials**

In 2009, Heymen et al randomly assigned 168 individuals with fecal incontinence to 3 months of biweekly pelvic floor exercise training alone (n=85) or exercise training with manometric biofeedback (n=83). Twenty-two patients in the exercise-only group and 38 in the biofeedback group improved during a 4-week run-in period and did not participate further, leaving 63 in the exercise group and 45 in the biofeedback group. The primary efficacy outcome was decrease in scores on the Fecal Incontinence Severity Instrument (FISI), a validated 4-item scale, from the end of run-in to 3 months. The analysis included all patients who completed at least 1 treatment (15 patients dropped out). The authors reported a greater reduction in FISI scores in the biofeedback group than in the exercise-only group (p=0.01; exact scores were not reported). Complete continence (no staining) was reported by 13 (21%) of 63 patients in the exercise-only group and 20 (44%) of 45 in the biofeedback group; this difference was statistically significant (p=0.008). A study limitation was that only 108 (64%) of 168 randomized patients received the intervention and, therefore, baseline imbalances in the treatment groups might have affected study outcomes. A stronger design would be to randomize patients after, not before, a run-in period.

In 2011, Bartlett et al in Australia published an RCT with 72 participants comparing 2 exercise regimens used with biofeedback for fecal incontinence. The trial did not find significant differences in outcomes with the 2 types of exercises. It is not possible to draw conclusions about the efficacy of biofeedback from this study's findings because all participants received biofeedback.

Norton et al (2003) randomly assigned 171 patients with fecal incontinence to 1 of 4 treatment groups: standard care (advice), advice plus instruction on sphincter exercises, hospital-based computer-assisted sphincter pressure biofeedback, and hospital biofeedback plus the use of a home EMG biofeedback device. Outcomes included diary reports of incontinence, quality of life, and anal manometry measurements. The authors reported that biofeedback yielded no greater benefit than standard care.

Solomon et al (2003) randomly assigned 120 patients with mild-to-moderate fecal incontinence to 1 of 3 treatment groups: biofeedback with anal manometry, biofeedback with transanal ultrasound, or pelvic floor exercises with feedback from digital examination alone. There were no significant differences in outcomes among the treatment groups; all reported modest improvements.
Children
A Cochrane review of behavioral and cognitive interventions for children with fecal incontinence was published in 2006 and updated in 2011.8,9 Of 21 included studies, 9 compared conventional treatment alone (ie, laxatives, toilet training, dietary advice) with conventional treatment plus biofeedback. Eight trials included children with functional fecal incontinence, and the ninth included children with fecal incontinence due to myelomeningocele (n=12). Four trials included children who had fecal incontinence due to constipation, and 3 others included children who had fecal incontinence due to constipation and pelvic floor dyssynergia. When data from the 9 studies were combined, 133 (51%) of 260 children in the conventional treatment plus biofeedback group were not cured or improved at follow-up compared with 121 (48%) of 250 children in the conventional treatment-only group. In a meta-analysis (random effects), this difference was not statistically significant (pooled OR=1.08; 95% CI, 0.63 to 1.84). The analysis combined 6- and 12-month follow-up data; 12-month data were used when available. Reviewers concluded that findings from RCTs did not support the claim that biofeedback training provides additional benefit to conventional treatment in the management of fecal incontinence associated with constipation. They also stated that, due to a lack of sufficient trials, they could not evaluate the effects of biofeedback in children with organic fecal incontinence.

Section Summary: Fecal Incontinence
The available evidence on biofeedback for fecal incontinence in adults and children includes RCTs and systematic reviews of those RCTs. Although the studies are characterized by heterogeneity of the interventions, comparators, and follow-up durations used, some studies demonstrated biofeedback was effective in improving symptoms of fecal incontinence. It may be a useful therapeutic option for patients who fail to respond to other treatments.

Constipation

Idiopathic Constipation, Not Specifically Dyssynergic Type

Adults
Several systematic reviews of RCTs have been published. Most recently, in 2014, a Cochrane review identified 17 trials (total N=931 patients) addressing the efficacy of biofeedback for treating adults with idiopathic constipation.10 Seven trials compared biofeedback with conventional nonsurgical treatment, 6 compared alternative approaches with biofeedback, 2 compared biofeedback with a surgical intervention, 1 compared biofeedback with electrical stimulation, and 1 used a sham control. Sample sizes ranged from 21 to 109 patients (mean, 48 patients per trial). Sixteen RCTs were judged to be at high risk of bias due to blinding of patients and outcome assessment. Blinding in the remaining study was unclear. Trials all used different biofeedback protocols and 11 used EMG biofeedback. Length of follow-up varied; 4 trials followed patients to the end of the intervention and 7 trials followed patients for 1 year. In most trials, a symptom scoring system was used as an outcome, with scores varying by symptoms included. Due to heterogeneity among trials, meta-analyses were not conducted. Reviewers concluded that there was insufficient evidence to draw conclusions about the efficacy of any particular biofeedback protocol used to treat chronic constipation in adults.

Previously, in 2009, the Enck systematic review (described in the Fecal Incontinence section) also reviewed the literature on biofeedback for constipation and conducted several meta-analyses.1 Eight RCTs conducted in adults were identified. Four compared 2 types of biofeedback; meta-analysis of these 4 studies did not find a significant benefit for 1 technique
over another (pooled OR=1.44; 95% CI, 0.69 to 3.09; p=0.32). The other 4 studies compared biofeedback with another treatment. Comparison treatments (1 study each) were botulinum toxin, laxatives, diazepam, and best supportive care (diet, exercise, laxatives). Two studies also included a third arm, in which treatment was a sham or placebo intervention. Three of the 4 studies included patients with dyssynergia-type constipation, and the fourth included patients with anismus. Meta-analysis of the 4 studies comparing 1 treatment with another (using the active intervention arm as the comparator in the 3-arm trials) found a significantly greater benefit of biofeedback in improving constipation symptoms (pooled OR=3.23; 95% CI, 1.88 to 5.58; p<0.001). Results of this systematic review were limited by heterogeneity in patient populations, comparator treatments, and outcome measures.

Children
No systematic reviews or meta-analyses on biofeedback for constipation in children, not associated with fecal incontinence, were identified. The literature search did identify the 1 RCT published since 2000. In 2001, van Ginkel et al selected 212 Dutch children at least 5 years old with constipation who met at least 2 of the following 4 criteria: (1) stool frequency fewer than 3 times per week; (2) 2 or more soiling and/or encopresis episodes per week; (3) periodic passage of very large amounts of stool every 7 to 30 days; or (4) a palpable abdominal or rectal fecal mass.11 Participants were randomly assigned to 6 weeks of standard treatment (ie, education, laxatives [n=111] or standard treatment plus 2 sessions of anorectal manometry [n=91]. During the manometry sessions, children were asked to squeeze the sphincter as tightly as possible 5 times. Squeeze pressure data were digitally converted; data could be viewed on a computer by the child and parent. Data were discussed after the sessions, and instructions were given on how to perform defecation exercises at home. Ten (5%) of 212 randomly assigned patients did not receive treatment; the remainder completed the intervention. Treatment success was defined as achieving 3 or more bowel movements per week and fewer than 1 soiling and/or encopresis episodes per 2 weeks while not receiving laxatives. At 6 weeks, 4 (4%) of 111 in the standard treatment group and 6 (7%) of 91 in the biofeedback group were considered to have successful treatment; this difference was not statistically significant. There was also no statistically significant difference between groups at any other follow-up point. At the final follow-up, 36 (43%) of 83 patients in the standard treatment group and 23 (35%) of 65 in the biofeedback group were considered treatment successes. Data on 30% of randomized patients were missing at final follow-up. This trial did not control for nonspecific effects of biofeedback.

Section Summary: Idiopathic Constipation, Not Specifically Dyssynergic Type
For adults with idiopathic constipation, the evidence for biofeedback consists of multiple randomized trials, which have been summarized in several systematic reviews. Although evidence is limited by the heterogeneity of patient populations, comparator groups, and outcome measures, some studies demonstrated improvement in constipation symptoms with biofeedback therapy.

Dyssynergic Constipation
Heymen et al (2007) assessed adults who met Rome II diagnostic criteria for pelvic floor dyssynergia, had at least 2 symptoms of functional constipation for at least 12 weeks in the past year, and had manometry or EMG findings consistent with chronic constipation (eg, evidence of inadequate propulsive forces and incomplete evacuation).12 Patients participated in a 4-week run-in period comprising education on diet and exercise and provision of fiber and stool softeners. Those who still met eligibility criteria at the end of the run-in period (84/117 [72%]) were randomly assigned to EMG biofeedback (n=30), diazepam 5 mg
(n=30), or placebo medication (n=24). All participants were trained to perform pelvic floor exercises and received 6 biweekly visits over 3 months, each lasting approximately 50 minutes. Patients and investigators were blinded to which patients received active versus placebo medication but not to whether they received biofeedback. In an intention-to-treat (ITT) analysis after the 3-month intervention, the proportion of patients reporting adequate relief of constipation symptoms was 70% in the biofeedback group, 23% in the diazepam group, and 38% in the placebo group; biofeedback had a significantly greater benefit when compared with diazepam (p<0.001) or placebo (p<0.017). A strength of this study design was its attempt to control for nonspecific effects of biofeedback (eg, increased contact with a health care provider, lifestyle modification advice), by including a run-in period and similar follow-up visits for all groups. Moreover, randomization did not occur until after the run-in period, so treatment groups were more likely to be similar at the start of the treatment phase.

Rao et al (2007) included patients who met Rome diagnostic criteria for functional constipation, had dyssynergia-type constipation, and, when expelling a simulated stool, had either prolonged difficulty (at least 1 minute) or prolonged delay (at least 20% marker retention in colonic transfer).13 All participants had failed routine management of constipation. Seventy-seven patients were randomly assigned to receive 3 months of standard therapy: education and dietary advice (n=24), standard therapy and biofeedback therapy (n=28), or standard therapy and sham feedback (n=24). Patients receiving active biofeedback received up to 6 biweekly 1-hour sessions: training was performed using a rectal manometry probe and software for displaying biofeedback data. In the sham treatment group, patients also used a rectal manometry probe but did not receive visual and verbal feedback. Patients were not blinded to treatment group, but the manometry reader was unaware of treatment assignment. In ITT analysis, after the 3-month intervention, patients in the biofeedback group reported a significantly greater increase in complete spontaneous bowel movements than the sham feedback group (p<0.05) and the standard treatment group (p<0.062). Additionally, a greater proportion of patients in the biofeedback group reported improved global bowel satisfaction compared with the sham feedback group (p=0.04), but the difference from the standard treatment group was not statistically significant. (The authors did not report exact numbers for either of these preceding primary analyses.) For primary physiologic parameters, ITT analysis found that the dyssynergia pattern was corrected in 79% of those in the biofeedback group, 4% in the sham group, and 8% in the standard treatment group. This difference was statistically significant in favor of the biofeedback group compared with the other groups (p<0.001 for both analyses). Moreover, balloon expulsion time during simulated defecation decreased significantly more in the biofeedback group than in the sham (p=0.003) or standard treatment (p=0.03) groups (exact times not reported for ITT analysis).

In a follow-up publication, Rao et al reported on 1-year findings for 13 (62%) of 21 patients in the biofeedback group and 13 (57%) of 23 in the standard treatment group.14 Patients in the sham group were not included in this follow-up. The extension study included visits at 3-month intervals, with additional advice provided as needed. Seven (54%) of the 13 biofeedback patients and all 13 patients in the standard treatment group completed 1-year follow-up. Mean change in complete spontaneous bowel movements (the primary outcome) favored the biofeedback group (increase, 2.9) compared with the standard treatment group (decrease, 0.2). The follow-up study suggested longer term effectiveness of biofeedback for this patient population. Although small numbers of patients who completed 1-year follow-up limits conclusions that can be drawn.

Section Summary: Dyssynergic Constipation
For patients with dyssynergic constipation treated with biofeedback, several RCTs have reported improvements in constipation symptoms.

**Summary of Evidence: Fecal Incontinence and Constipation**

There is evidence in randomized controlled trials (RCTs) and systematic reviews demonstrating biofeedback techniques are safe and effective in the treatment of fecal incontinence, especially for patients who do not respond to conservative treatment.

Evidence for dyssynergia-type constipation treated with biofeedback includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Several well-conducted RCTs focusing on patients with dyssynergia-type constipation have reported benefits in a subgroup of patients meeting well-defined criteria.

Evidence for constipation other than dyssynergia-type treated with biofeedback includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A systematic review of RCTs found a benefit of biofeedback as a treatment for constipation in adults.

Published guidelines and recommendations support biofeedback therapy for the treatment of constipation.

**Headache**

This evidence review was originally based on a 1995 TEC Assessment,¹ and has since been updated periodically using the MEDLINE database. The most recent literature review is below.

**Adults**

A 2007 book chapter on integrative medicine states that biofeedback as part of a stress management program can provide significant benefit for patients with migraine and tension-type headache without adverse effects.² Meta-analysis of 25 controlled studies suggested that biofeedback is comparable with preventive pharmacotherapy. Another meta-analysis of 5 studies revealed a 37% improvement in headache symptoms associated with thermal biofeedback. There are no established criteria for predicting benefit, and training requires a significant time commitment (eg, 10 to 15 hour-long sessions plus home practice). Pharmacotherapy combined with biofeedback has not been studied for synergy. This is an important point because vascular reactivity (a major target in biofeedback training) may be modified by medications used for prevention (eg, β-blockers), potentially limiting the effects of training.

In 2007 and 2008, Nestoriuc et al in Germany published systematic reviews of biofeedback for migraine and tension-type headaches.³ ⁴ Meta-analysis for the treatment of migraine included 55 studies (randomized, pre-post, uncontrolled) and 39 controlled trials, reporting a medium effect size of 0.58 (pooled outcome of all biofeedback interventions) for treatment of migraine.³ Effect sizes were computed using Hedges' g, which quantifies between-group treatment outcome differences (mean difference between groups divided by the pooled standard deviation). For treatment of tension-type headaches, 53 studies met criteria for analysis; these included controlled studies with standardized treatment outcomes, follow-up of at least 3 months, and at least 4 patients per treatment group.⁴ Meta-analysis showed a medium-to-large effect size of 0.73 that appeared to be stable over 15 months of follow-up. Biofeedback was reported to be more effective than headache monitoring, placebo, and relaxation therapies.
Biofeedback in combination with relaxation was more effective than biofeedback alone, and biofeedback alone was more effective than relaxation alone, suggesting different elements for the two therapies. Although these meta-analyses are limited by the inclusion of studies of poor methodologic quality, the authors did not find evidence of an influence of study quality or publication bias in their findings.

Verhagen et al in The Netherlands published a systematic review of behavioral treatments for chronic tension-type headache in adults in 2009.5 Eleven studies, including 2 studies with low risk of bias, compared biofeedback with waiting-list conditions. Results were found to be inconsistent due to low power, leading the authors to conclude that larger and more methodologically robust studies should be performed.

Martin et al (2007) in Australia compared cognitive-behavioral therapy (CBT) versus temporal pulse amplitude (TPA) biofeedback (8 weekly sessions plus homework) or waiting-list control among patients who volunteered for a study of psychologic treatments.6 Of 64 enrolled patients, 51 completed the protocol (20% dropout) with no significant difference in loss to follow-up among the groups; 30 patients with migraine and 21 with tension-type headaches were randomized to 1 of the 3 treatments. Patient logs showed an average reduction in headaches of 68% for the CBT group, 56% for biofeedback, and 20% for the control condition. Clinically significant improvement, defined as at least 50% reduction in either headache rating or medication use, was observed in 78% of the CBT group, 63% of the biofeedback group, and 23% of the control group. Cognitive mediators (self-efficacy, locus of control) that had been hypothesized to underlie efficacy of both biofeedback and CBT were not found to be associated with improvement for either treatment. Statistical analysis was limited by small group sizes.

Some studies indicate that the physiologic parameter “fed back” to the patient may not be related to the pathophysiology of headache. For example, Andrasik and Holroyd (1983) examined the correlation between success in controlling scalp muscle tension and reduction in headache symptoms.7 Thirty patients with tension headaches were taught to decrease, keep stable, or increase frontal muscle tension but were all led to believe that they were decreasing muscle tone. Despite changes in muscle tone in the intended direction, the degree of headache relief was the same in all groups. A similar study in 1980 showed that patients who were told that they were successful at decreasing muscle tension, regardless of actual results, achieved greater reduction in symptoms.8 Similar results were reported in 1989 for patients with migraine undergoing thermal biofeedback.9

Children
A 2006 meta-analysis by Trautmann et al in Germany assessed psychologic treatments of recurrent tension headache or migraine in children.10 Three studies were included that compared relaxation combined with biofeedback versus relaxation training alone. In general, small standardized effect sizes (0, 0.5, 0.25) were reported from the three studies for the effect of biofeedback on headache symptoms (frequency, intensity, duration of headache). Small standardized effect sizes were also reported for clinically significant changes (ie, >50% reduction) in headache symptoms (0.20, 0.34, 0). A 2006 systematic review of nonpharmacologic treatments for migraine concluded that the literature at that time did not show clear effectiveness of biofeedback for migraine in children.11

A 2009 Cochrane review evaluated psychologic therapies for the management of chronic and recurrent pain in children and adolescents.12,13 Twenty-one randomized controlled trials (RCTs) met inclusion criteria for the analysis on headache, including 3 trials with biofeedback and
relaxation training and 3 trials with biofeedback and cognitive training. Clinically significant pain reduction was found with biofeedback (odds ratio, 23.34), but there was no significant effect on disability or emotional functioning. The authors concluded that psychologic treatments (including biofeedback as part of a treatment regimen) are effective in pain control for children with headache, and the benefits appear to be maintained.

In 2010, Gerber et al reported an RCT of a multimodal behavioral training program (n=19) compared with the “benchmark” of biofeedback (n=15) in pediatric patients 7 to 16 years of age with recurrent migraine and/or tension-type headache. Patients with chronic daily headache (≥15 d/mo) were excluded from the study. The multimodal behavioral training program included eight 90-minute sessions of training (diagnostic, educational, behavioral) for the children and four 120-minute sessions for their parents. Children in the biofeedback group underwent electromyographic (EMG) and thermal biofeedback once weekly for 20 sessions (total of 900 minutes of training). During treatment, 5 patients withdrew because of difficulty with adherence (4 from the biofeedback group). At 6 months, children’s diaries indicated a 47% decrease in the intensity of headaches after biofeedback but no significant difference in the frequency or duration of headaches. Diary results are limited by the low (40%) completion rate. Questionnaire results from parents and children indicated a decrease in headache duration, frequency, and intensity. Diaries of daily living activities and a pediatric quality-of-life questionnaire indicated that after treatment, the children were less disturbed by their headaches in the domains of school, homework, and leisure time. There were no significant differences between treatment groups, although power analysis indicated that 50 patients per group would be needed to detect differences.

Earlier work includes a study by Kroner-Herwig et al in Germany in 50 pediatric patients with either tension headaches or combined tension-migraine headaches. Four treatment groups were created, based on combinations of the presence or absence of parental involvement in treatment and whether patients received either relaxation training or biofeedback. A waiting-list control group was also included. Several analytic approaches were used, one of which found biofeedback to have better effects on pain than relaxation. Another study by Bussone et al in Italy compared biofeedback-assisted relaxation training in adolescents versus a control group, finding better pain improvement in the former group. Scharff et al in the United States enrolled 36 children and adolescents and randomized them to hand-warming biofeedback, to hand-cooling biofeedback, or to a waiting list. Patients treated with hand-warming biofeedback achieved greater degrees of clinical improvement than either of the other two groups. Hand-cooling biofeedback could be considered a placebo. Sartory et al in Germany randomly assigned 43 children to either relaxation training plus stress management, biofeedback plus stress management, or drug therapy with a beta-adrenergic blocking agent. Both the relaxation and biofeedback groups had better therapeutic outcomes than the drug therapy group.

**Summary of Evidence: Headache**

The literature on biofeedback, which includes systematic reviews of a large number of controlled and uncontrolled studies, suggests that this treatment may reduce the number and/or severity of migraine and tension-type headaches. In addition, clinical input and physician specialty society recommendations strongly support the use of biofeedback to treat migraine and tension-type headaches when included in a comprehensive treatment program. Evidence is insufficient to evaluate the effect of biofeedback on cluster headaches. Biofeedback, along with other psychologic and behavioral techniques, such as relaxation
training, may be particularly useful for children, pregnant women, and other adults who are not able to take medications.

**Chronic Pain**

This evidence review was originally based on a 1995 TEC Assessment, which concluded that evidence was insufficient to demonstrate the effectiveness of biofeedback for treatment of chronic pain.¹ The evidence review has been updated regularly with searches of the MEDLINE database. Following is a summary of the key literature to date.

Psychological treatments involve both nonspecific and specific therapeutic effects. Nonspecific effects, sometimes called placebo effects, occur as a result of contact with the therapist, positive expectancies on the part of the patient and therapist, and other beneficial effects that occur as a result of the patient being in a therapeutic environment. Specific effects are those that occur only because of the active treatment, beyond any nonspecific effects that may be present. The literature review focuses on identifying evidence that the effects of biofeedback are distinct from nonspecific placebo effects. Because establishing an ideal placebo control is problematic with psychological treatments and because treatment of chronic pain is typically multimodal, isolating the specific contribution of biofeedback is challenging. An ideal study design would be a randomized controlled trial (RCT) comparing biofeedback with a sham intervention; an alternative design would be an RCT comparing an intervention such as exercise with and without the addition of biofeedback.

Several meta-analyses were identified that reviewed RCTs on psychological therapies for a variety of nonheadache chronic pain conditions. A 2009 Cochrane systematic review by Eccleston et al focused on chronic pain in adults.² Two RCTs were identified that compared behavioral therapy against an active control designed to change behavior (ie, exercise or instruction). Three RCTs had sufficient follow-up to be included in a comparison of behavioral therapy versus usual treatment. The systematic review found that although the quality of trial design had improved over time, there were too few studies to achieve a meaningful conclusion about the effects of behavioral therapy on pain, disability, or mood.

Another 2009 Cochrane review by Eccleston et al focused on children and adolescents with chronic and recurrent pain.³ Although psychological therapies were found to improve pain, only 1 of the 5 studies on nonheadache pain evaluated biofeedback. Biofeedback was not found to improve abdominal pain more than cognitive-behavioral therapy (CBT) in this trial (published by Humphreys and Gevirtz⁴; see section on Abdominal Pain). In 2010, Palermo et al published an updated meta-analysis of studies on psychological therapies for management of chronic pain in children and adolescents.⁵ The review did not identify any new RCTs on biofeedback for managing nonheadache pain.

**RCTs and Meta-Analyses on Biofeedback for Specific Chronic Pain Conditions**

**Low Back Pain**

A 2010 Cochrane review on behavioral treatments for chronic low back pain included a meta-analysis of 3 small randomized trials that compared electromyography (EMG) biofeedback to a waiting-list control group.⁶ In the pooled analysis, there were a total of 34 patients in the intervention group and 30 patients in the control group. The standard mean difference in short-term pain was -0.80 (95% confidence interval [CI], -1.32 to -0.28); this difference was statistically significant favoring the biofeedback group. The Cochrane review did not conduct
meta-analyses of trials comparing biofeedback with sham biofeedback and therefore was not able to control for any nonspecific effects of treatment.

At least 1 RCT has compared biofeedback with a sham intervention for treatment of low back pain. In 2010, an RCT by Kapitza et al compared the efficacy of respiratory biofeedback with sham biofeedback in 42 patients with low back pain. All participants were instructed to perform daily breathing exercises with a portable respiratory feedback machine; exercises were performed for 30 minutes on 15 consecutive days. Patients were randomized either to an intervention group that received visual and auditory feedback of their breathing exercises or to a control group that received a proxy signal imitating breathing biofeedback. Patients recorded pain levels in a diary 3 times a day, measuring pain on a visual analog scale (VAS). Both groups showed reduction in pain levels at the end of the intervention period and at 3-month follow-up although between-group differences were not statistically significant. For example, 3 months after the intervention, mean change in pain with activity was a reduction of 1.12 points on a 10-point VAS in the intervention group and 0.96 points in the sham control group (p>0.05); mean change in pain at rest was a reduction of 0.79 points in the intervention group and 0.49 points in the control group (p>0.05).

Several trials with active comparison groups have not found that biofeedback is superior to alternative treatments. An article published by Glombiewski et al in 2010 assessed whether the addition of EMG biofeedback to CBT improved outcomes in 128 patients with low back pain. Patients were randomized to one of 3 groups: CBT, CBT plus biofeedback, or a waiting-list control. Although both treatments were found to improve outcomes including pain intensity compared with a waiting-list control (moderate effect size of 0.66 for pain intensity in the CBT plus biofeedback group). However, the addition of biofeedback did not improve outcomes over CBT alone.

More recently, in 2015, Tan et al evaluated 3 self-hypnosis interventions and included EMG biofeedback as a control intervention. The study enrolled 100 patients with chronic low back pain. After the 8-week intervention, reported reductions in pain intensity were significantly higher in the combined hypnosis groups compared with the biofeedback group (p=0.042).

**Chronic Knee Pain**

In 2012, Collins et al published a systematic review and meta-analysis of RCTs on nonsurgical interventions for anterior knee pain. In a pooled analysis of data from 2 trials, there was no significant benefit of adding EMG biofeedback to an exercise-only intervention at 8 to 12 weeks (standard mean difference [SMD], -22; 95% CI, -0.65 to 0.20).

**Chronic Neck and Shoulder Pain**

In 2011, Ma et al in Hong Kong published an RCT that included 72 patients with chronic (at least 3 months) computer work-related neck and shoulder pain. Patients were randomized to 1 of 4 interventions that continued for 6 weeks: biofeedback, exercise, passive treatment (eg, hot packs), or a control group receiving only an educational pamphlet. Members of the biofeedback group were given a portable EMG biofeedback machine and were instructed to use it for 2 hours daily while performing computer work. The exercise group was given an active routine to perform on their own for no longer than 20 minutes, 4 times a day. At the postintervention follow-up, 60 of 72 participants (83%) were available for assessment (n=15 per group). By the end of the intervention, the average scores pertaining to the VAS and neck
disability index (NDI) were significantly lower in the biofeedback group than in the other 3
groups. For example, the mean (SD) VAS score postintervention was 1.87 (0.74) in the
biofeedback group and 2.10 (1.34) in the exercise group (p<0.05).

Although this study found a short-term benefit of a biofeedback intervention, the magnitude of
difference in the VAS and NDI scores was small and of uncertain clinical significance. In
addition, there were several methodologic limitations. The study included a small sample size
and had a substantial number of dropouts. The interventions were not balanced in intensity; for
example, the biofeedback intervention was more intensive (2 h/d) than some other
interventions (eg, passive treatment arm), which received two 15-minute sessions per week.
Long-term data were not available due to the low rate of follow-up; at 6 months, data were
available on only 39 (54%) of 72 of participants, which was too small for meaningful analysis.

Orofacial Pain
A 2011 Cochrane review by Aggarwal et al identified 17 trials evaluating nonpharmacologic
psychological interventions for adults with chronic orofacial pain (eg, temporomandibular joint
[TMJ] disorder).12 For studies reporting on short-term pain relief (≤3 months), a significantly
greater reduction in pain was found for interventions that combined CBT and biofeedback
compared with usual care (2 studies; SMD=0.46; 95% CI, 0.02 to 0.90). However, when the
authors reviewed results from studies reporting on long-term pain relief (>6 months), no
significant benefit was found with a combined intervention of CBT/biofeedback and there were
no studies that compared CBT alone versus CBT plus biofeedback. For studies reporting on
biofeedback-only interventions, a pooled analysis of 2 studies on short-term pain relief did not
find a significant benefit compared with usual care (SMD = -0.41; 95% CI, -1.06 to 0.25). There
was only 1 study reporting long-term pain relief after a biofeedback-only intervention, so a
pooled analysis could not be done. The authors concluded that there is weak evidence to
support psychosocial interventions for managing chronic orofacial pain and the most promising
evidence is for CBT, with or without biofeedback. They noted that the trials comprising the
review were few in number and had a high risk of bias, and they recommended additional high-
quality trials be conducted.

The conclusions drawn from this Cochrane review are similar to previous systematic reviews
on treatment of TMJ disorder.13,14 These reviews also concluded that there is weak evidence
that psychosocial/physical therapy interventions (including biofeedback) are beneficial for
treating TMJ disorder and that of the few studies available, they tended to be of poor
methodologic quality.

Fibromyalgia
In 2013, Glombiewski et al published a meta-analysis and systemic review of RCTs reporting
data on the efficacy of EMG and electroencephalography (EEG) biofeedback (ie,
neurofeedback) for treating patients with fibromyalgia.15 The authors identified 7 RCTs that
compared EEG biofeedback with a control method in patients with fibromyalgia syndrome.
Studies in which biofeedback was evaluated only as part of multicomponent interventions were
excluded from the review. Three studies used EEG biofeedback and 4 used EMG biofeedback,
yielding a total of 321 patients. A sham intervention was used as a control condition in 4
studies, 2 using EEG biofeedback and 2 using EMG biofeedback. In a pooled analysis of the
studies using EMG biofeedback, a significant reduction in pain intensity was found compared
with a different intervention (effect size, Hedges g=0.86; 95% CI, 0.11 to 0.62). A pooled
analysis of studies on EEG biofeedback did not find a significant benefit in pain reduction
compared with control methods. Pooled analyses of studies of EMG and EEG biofeedback did
not find a significant benefit of either intervention on other outcomes such as sleep problems, depression, and health-related quality of life. None of the studies included in this review were of high quality, with risk of bias assigned by the authors being either unclear or high for all included studies. In addition, all of the studies reported on short-term outcomes, resulting in a lack of evidence on whether longer term outcomes are improved with these interventions.

Representative RCTs on EMG biofeedback include a 1998 trial by Buckelew et al, which enrolled 119 patients with fibromyalgia and was one of the larger trials; however, the trial did not follow a double-blind design. Patients were randomly assigned to 1 of 4 treatment groups: (1) biofeedback/relaxation training, (2) exercise training, (3) combination treatment, and (4) an educational/attention control program. While the combination treatment group had better tender point index scores than other treatment groups, this study did not address placebo effects or the impact of adding biofeedback to relaxation therapy. In another large, unblinded RCT that was published in 2002, van Santen et al evaluated 143 women with fibromyalgia, and biofeedback was compared with fitness training and with usual care. The primary outcome was pain using a VAS. Compared with usual care, the authors reported no clear improvements in objective or subjective patient outcomes with biofeedback (or fitness training). In a small, double-blind RCT from Asia, actual and sham biofeedback were compared for effects on pain, fitness, function, and tender points in 30 patients with fibromyalgia. Pain reduction as assessed on a VAS did not differ significantly between groups. The authors calculated that a sample size of 15 patients could detect a difference of 5 cm (on a 10-cm scale) on a VAS, suggesting that the study lacked adequate power.

Abdominal Pain
In an study by Humphreys and Gevirtz (2000), 64 children and teenagers with diagnosed recurrent abdominal pain were randomly assigned to groups treated with increased dietary fiber; fiber and biofeedback; fiber, biofeedback, and CBT; or fiber, biofeedback, CBT, and parental support. The similar nature of the 3 multicomponent treatment groups was associated with better pain reduction than the fiber-only group. This study did not address placebo effects. In a 2003 systematic review of therapies for recurrent abdominal pain in children by Weydert et al, the behavioral interventions of CBT and biofeedback had a general positive effect on nonspecific recurrent abdominal pain and were deemed safe. The specific effects of biofeedback were not isolated in this systematic review and therefore cannot be assessed.

Arthritis
A 2012 systematic review by Macfarlane et al evaluated practitioner-based complementary and alternative medicine treatments (defined as any treatment not taken orally or applied topically) for osteoarthritis and identified 2 trials on biofeedback. One was an RCT from 2010 that assessed whether the addition of EMG biofeedback to strengthening exercises improved outcomes in 40 patients with knee osteoarthritis. After a 3-week treatment period, no significant differences between the 2 treatment methods relative to pain or quality of life were found. The other RCT, published in 2007, compared electrical stimulation with biofeedback-assisted exercise in 50 women with knee osteoarthritis. After 4 weeks of treatment, there were no statistically significant differences between groups in pain and functioning scores.

Systemic Lupus Erythematosus
In a 2004 RCT by Greco et al, of 92 patients with systemic lupus erythematosus (SLE), those treated with 6 sessions of biofeedback-assisted CBT for stress reduction had statistically significant greater improvements in pain posttreatment than a symptom-monitoring support.
group (p=0.044) and a group receiving usual care (p=0.028). However, these improvements in pain were not sustained at 9-month follow-up, and further studies are needed to determine the incremental benefits of biofeedback-assisted CBT over other interventions in patients with SLE.

**Vulvar Vestibulitis**
A 2001 randomized study by Bergeron et al of 78 patients with dyspareunia resulting from vulvar vestibulitis compared treatment with EM biofeedback, surgery, or CBT. Patients who underwent surgery had significantly better pain scores than patients who received biofeedback or CBT. No placebo treatment was used.

**Summary of Evidence: Chronic Pain**
The evidence for biofeedback in patients who have chronic pain includes multiple randomized controlled trials (RCTs) for different pain syndromes. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The results of these RCTs, some of which are sham-controlled, do not consistently report benefit for biofeedback. Some RCTs have reported improved outcomes with biofeedback, but these improvements are often of uncertain clinical significance or are not durable. Many other RCTs have found that biofeedback did not provide a significantly greater benefit in outcomes when it was used either instead of or in addition to other conservative interventions such as exercise. Overall, the available RCTs were limited by small sample sizes and high dropout rates. This evidence base does not allow conclusions about the specific effects of biofeedback beyond the nonspecific effects of sham interventions, nor does it allow conclusions about the contribution of biofeedback beyond that of other conservative treatments for pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Miscellaneous Indications**
A 1995 TEC Assessment concluded that evidence was insufficient to demonstrate the effectiveness of biofeedback for treatment of 9 conditions: anxiety disorders, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia.

**Anxiety**
In 2017, Goessl et al published a meta-analysis on the effect of heart rate variability (HRV) biofeedback training on patients with stress and anxiety. HRV is a measure of cardiac vagal tone. Low HRV is associated with certain psychological states such as anxiety. The literature search identified 24 studies (total N=484 patients), published between 1976 and 2015, for inclusion. Sample sizes ranged from 5 to 106 patients (median, 14 patients). The Cochrane on risk of bias tool was used to assess study quality. Many studies had high or unclear risk of bias due to: inadequate randomization descriptions, improper randomization, undescribed allocation concealment, and missing data that was either not described or mishandled. Thirteen studies included a comparison group (6 waitlist, 3 standard of care, 2 sham, 1 daily thought record, 1 progressive muscle relaxation). The average within-group effect size among the 24 studies, measured by Hedges’ $g$, was 0.81, indicating a large effect on anxiety. The average between-group effect size among the 13 studies with comparators, also measured by Hedges’ $g$, was 0.83, indicating HRV had a larger effect on anxiety than the comparators.

In 2014, Canadian Agency for Drugs and Technology in Health (CADTH) published a rapid response report on biofeedback for treating mood and anxiety disorders. Their systematic
review of the literature did not identify any health technology assessments systematic reviews, meta-analyses, RCTs, or nonrandomized studies evaluating biofeedback for the treatment of generalized anxiety disorder.

Randomized Controlled Trials
In 2016, Chen et al published an RCT comparing diaphragmatic breathing relaxation (DBR) with routine respiration activities in the treatment of patients with anxiety. DBR is a technique that uses the diaphragm muscle contraction to force air downward into the body, increasing diaphragm length and breathing efficiency. Outcomes were anxiety level, measured by Beck Anxiety Inventory and 4 physiologic measures (skin conductivity, peripheral blood flow, heart rate, breathing rate). All patients participated in an individualized 8-week course in breathing relaxation. Fifteen were randomized to DBR training and 15 to routine breathing relaxation training. Researchers and patients were blinded to randomization, with only the trainer being aware of group allocation. After 8 weeks, the DBR group experienced statistically significant decreases in Beck Anxiety Inventory scores compared with baseline, while the control group did not experience significant decreases from baseline. The DBR group also experienced significant improvements in all 4 physiological measurements and the control group did not.

Section Summary: Anxiety Disorders
A systematic review on HRV biofeedback found that this technique had a positive effect on anxiety levels, though the studies had small sample sizes and in general were of poor quality. An RCT evaluating diaphragmatic breathing relaxation also found a positive effect on anxiety, though this trial also had a small sample size. Additional higher quality research with larger sample sizes is needed.

Asthma
In 2015, Yorke et al published a systematic review of studies evaluating nonpharmacologic interventions for the treatment of adults with asthma. The literature search, conducted through May 2014, identified 23 studies for inclusion. The nonpharmacologic interventions were organized into 4 groups: relaxation-based therapies (n=9); cognitive behavioral therapies (n=5); multicomponent interventions (n=5); biofeedback techniques (n=3); and mindfulness (n=1). The 3 biofeedback RCTs used different techniques: exhaled carbon dioxide capnography (N=12); HRV using a physiograph (N=94); and respiratory sinus arrhythmia by ECG feedback and muscle tension by electromyography (N=17). Common outcomes in the 3 studies included peak expiratory flow and respiratory impedance. Two of the trials reported on medication use. While differences were detected in exhaled carbon dioxide, HRV, and muscle tension, no changes in forced expiratory volume in 1 second (FEV1) were found and medication use decreased in only 1 trial. Reviewers concluded that larger sample sizes were needed to demonstrate effects and that while certain parameters that patients received biofeedback on may have differed between treatment groups, those differences did not translate into meaningful clinical benefits.

Section Summary: Asthma
A recent systematic review identified 3 studies using 3 biofeedback techniques to treat asthma. The studies reported improvements in the parameters that the patients received biofeedback on, but those improvements did not impact clinical benefits such as decreased medication use or increased forced expiratory volume.

Bell Palsy
In 2008, Cardoso et al published a systematic review of studies on the effects of facial exercises on symptoms of Bell palsy. Studies including patients with unilateral idiopathic facial palsy treated with facial exercises associated with mirror and/or electromyographic (EMG) biofeedback were included in this review. Four studies (N=132) met the eligibility criteria. The studies described mime therapy versus control (n=50), mirror biofeedback exercise versus control (n=27), "small" mirror movements versus conventional neuromuscular retraining (n=10), and EMG biofeedback plus mirror training versus mirror training alone. The treatment length varied from 1 to 12 months. The authors concluded that “…because of the small number of randomized controlled trials, it was not possible to analyze if the exercises, associated either with mirror or EMG biofeedback, were effective. In summary, the available evidence from randomized controlled trials is not yet strong enough to become integrated into clinical practice.”

**Section Summary: Bell Palsy**
A systematic review identified 4 studies using 4 biofeedback techniques to treat Bell palsy. Sample sizes were small and there was heterogeneity in the techniques and length of treatments. The authors concluded that evidence is insufficient.

**Depression**
The 2014 CADTH report on biofeedback for mood and anxiety disorders, discussed under the Anxiety section, included a systematic review of the literature on biofeedback for depression. Other than 2 dissertations using heart rate biofeedback, no health technology assessments systematic reviews, meta-analyses, RCTs or nonrandomized studies evaluating biofeedback for the treatment of depression were identified.

Since the Canadian report, Hamilton et al (2016) published a randomized blinded study on neurofeedback training for patients with major depressive disorder. Twenty patients were shown negative pictures from the International Affective Picture System before and after neurofeedback training. Ten patients were randomized to their neural response data and the remaining 10 patients to neural response data that was not their own (sham). All patients were told that they would receive neurofeedback signals indicating their emotional responses to the negative pictures and that they should adopt strategies such as cognitive reappraisal, attentional redirection, and imagery to decrease their emotional response. Patients receiving their real neural response feedback, were able to greater decrease their emotional responses postintervention compared to patients receiving the sham neural response feedback. This was a proof of concept study and additional research with larger sample sizes is needed.

**Section Summary: Depression**
A small RCT using neurofeedback training for the treatment of major depressive disorder was identified. The results were positive and additional research with larger sample sizes is needed.

**Hypertension**

**Systematic Reviews**
A systematic review of studies on biofeedback for hypertension was published by Greenhalgh et al in 2010. Reviewers searched for RCTs that included adults with essential hypertension (defined as at least 140/90 mm Hg) and that compared biofeedback interventions, alone or in combination with other therapies, to medication, sham biofeedback, no treatment, or another behavioral intervention. A total of 36 trials (N=1660) met inclusion criteria. Trials generally had
small sample sizes; only 4 included more than 100 patients. All were single-center, and most were conducted in the United States. Trials used a variety of biofeedback techniques including thermal biofeedback, galvanized skin response, pulse wave velocity, and heart rate variability; some trials used more than 1 modality. Twenty studies evaluated biofeedback alone, 15 evaluated biofeedback combined with another intervention, and 1 had multiple arms and evaluated both types of interventions; only 4 trials included a sham biofeedback comparison group. The authors stated that they did not pool study findings due to differences in interventions and outcomes and the generally poor quality of the studies.

Reviewers reported that trials comparing biofeedback alone versus no treatment or another behavioral intervention did not provide convincing evidence of the superiority of biofeedback. Only 1 of 5 trials that compared a biofeedback combination intervention (most commonly combined with relaxation) with a different behavioral treatment found the biofeedback intervention to be superior. Approximately half of the trials comparing a biofeedback combination with no treatment found a significant benefit to the biofeedback combination, but the specific effects of biofeedback cannot be determined from this analysis. Only 1 trial was identified that compared a biofeedback combination intervention with sham biofeedback, and this study did not find a significant difference in the efficacy of the 2 interventions. Four studies on biofeedback alone and another 4 on a combined biofeedback intervention reported data beyond 6 months; most of these found no significant differences in efficacy between the biofeedback and control groups.

Randomized Controlled Trials
Wang et al (2016) published an RCT evaluating the effect of direct blood pressure biofeedback on patients with prehypertension or stage I hypertension.12 A trained nurse instructed patients in blood pressure self-regulation by using slow diaphragmatic breathing and passive attitude. During the 8-week training (1 session per week), patients in the treatment group received real-time blood pressure feedback signals (n=29) and controls received pseudo-feedback signals (n=28). Outcomes were systolic and diastolic blood pressure, measured at baseline and 1 and 8 weeks after training. Both groups significantly decreased blood pressure following training. The decreases were equal in magnitude, suggesting that blood pressure self-regulation training can effectively lower blood pressure, regardless of type of feedback signal.

Section Summary: Hypertension
Although there are a large number of RCTs evaluating biofeedback for treating hypertension, evidence is insufficient due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of trials, and the variability among interventions.

Motor Dysfunction After Stroke
Numerous RCTs and several systematic reviews of RCTs have been published. Systematic reviews have noted that RCTs tended to have relatively small sample sizes, and only small RCTs were identified in policy updates.13, 14 Recent systematic reviews and RCTs not included in the systematic reviews are discussed below.

Systematic Reviews
In 2017, systematic review and meta-analysis published in 2011 (see below) which evaluated the effect of biofeedback on lower limb activities in patients who have had a stroke.15 Only high-quality RCTs or quasi-RCTs with Physiotherapy Evidence Database (PEDro) scores greater than 4 were included. The literature search, conducted through September 2015, identified 18 trials (total N=429 patients) for inclusion. Training activities were walking (9 trials),
standing (8 trials), and standing up (1 trial). Trials were small, with study populations ranging from 12 to 50 patients. Biofeedback techniques included weight distribution from a force platform or sensor (11 trials), muscle activity from EMG (3 trials), linear gait parameters (3 trials), and joint angle from a goniometer (1 trial). Visual feedback was used in 7 trials, auditory in 7 trials, and a combination of visual/auditory in 4 trials. Pooled standard mean difference of the short term effect of biofeedback from 17 trials (n=417) was significant, at 0.50 (95% confidence interval [CI], 0.3 to 0.7). Long-term effects could not be calculated because only 4 trials provided that information.

A 2011 systematic review and meta-analysis by Stanton et al was updated in 2017. A total of 22 trials with 591 participants met inclusion criteria; in the update, reviewers only included high-quality trials (see above).

A systematic review by Zijlstra et al, published in 2010, focused on studies evaluating biofeedback-based training to improve mobility and balance in adults older than 60 years of age. Although the review was not limited to studies on motor function after stroke, more than half of the studies included older adults poststroke. For inclusion in this review, studies needed to include a control group of patients who did not receive biofeedback and to assess at least 1 objective outcome measure. A total of 97 potentially relevant articles were identified, and 21 (22%) studies, including 17 RCTs, met the selection criteria. Twelve of the 21 (57%) studies included individuals poststroke, 3 included older adults who had lower-limb surgery, and 6 included frail older adults without a specific medical condition. Individual studies were small; sample sizes ranged from 5 to 30 patients. The added benefit of using biofeedback could be evaluated in 13 of 21 (62%) studies. Nine of the 13 studies found a significantly greater benefit with interventions that used biofeedback compared with control interventions. However, the outcomes assessed were generally not clinical outcomes but were laboratory-based measures related to executing a task (eg, moving from sitting to standing) in a laboratory setting and platform-based measures of postural sway. Only 3 studies reported long-term outcomes, and none of these reported a significant effect of biofeedback.

Randomized Controlled Trials

In 2017, Kim published an RCT on the effect of EMG on upper-extremity functions in patients who have had a stroke. Patients were randomized to traditional rehabilitation therapy (n=15) or traditional rehabilitation therapy plus EMG biofeedback training (n=15). Upper-limb function was measured by Fugl-Meyer Assessment (FMA) and Manual Function Test (MFT), and activities of daily living were measured using the FIM instrument. Both FMA and MFT improved significantly more in the patients receiving EMG biofeedback. However, there was not a significant difference in the FIM score improvement between the 2 study groups.

In 2017, Yang published an RCT on the effect of biofeedback weight bearing training on the ability to sit/stand/sit and on stability among patients who have had a stroke. Patients were randomized to biofeedback weight bearing training (n=15) or functional weight-bearing training (n=15). Outcomes were time to sit/stand/sit and stability (measured by Biorescue which detects area of center of pressure). Comparison statistics were calculated for pre- and posttraining, and between treatment groups. Both outcomes significantly improved in the biofeedback group and did not improve significantly in the control group.

In 2016, Ghomashchi published an RCT evaluated the effect of visual biofeedback on postural balance disorders in patients who have had a stroke. Patients received conventional physical therapy and balance training exercises. During balance training, 16 patients were randomized
to visual biofeedback and 15 patients to no visual information. Outcomes were center of pressure and approximate entropy. Both groups experienced improvements in postural control, with no significant differences between the rehabilitation methods.

Section Summary: Motor Function After Stroke
The evidence base on biofeedback for improving motor function after stroke is limited by small studies, and there is variability in the type, duration, and intensity of interventions. In addition, the outcome measures used were primarily assessments of motor activity that were based in a laboratory or research setting. The applicability of improvements in these types of measures to clinical outcomes, such as the ability to perform ADLs or the rate of falls, is unknown. In addition, few studies have reported long-term outcomes. Conclusions about the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from the evidence published to date for the reasons previously discussed.

Motor Dysfunction After Injury or Lower-Limb Surgery
A 2010 systematic review by Silkman and McKeon evaluated the effectiveness of EMG biofeedback for improving muscle function during knee rehabilitation after injury.21 Four RCTs that compared knee rehabilitation exercise programs with and without biofeedback were identified. Sample sizes in individual studies ranged from 26 to 60 patients. Two of the 4 studies found a statistically significantly greater benefit in the programs that included biofeedback, and the other 2 did not find a significant difference between groups. The positive studies assessed intermediate outcomes (eg, contraction values of the quadriceps muscles). None of the studies were designed to assess functional outcomes.

Section Summary: Motor Dysfunction After Injury or Lower-Limb Surgery
A systematic review identified 4 RCTs. Evidence from these trials is limited due to small sample sizes, inconsistent results, and the measurement of intermediate outcomes rather than functional outcomes.

Multiple Sclerosis
A 2016 crossover study by van der Logt et al evaluated the effect of vibrotactile biofeedback of trunk sway on balance control in patients with multiple sclerosis.22 Ten patients performed a series of stance and gait tasks while trunk sway was measured using a SwayStar device attached to the waist. Patients underwent the series of tasks with and without an add-on to the SwayStar device which provided patients with direction-specific vibrotactile feedback during the tasks. When patients performed the tasks with vibrotactile biofeedback, there was a general reduction in trunk sway, though not all the reductions were significantly different compared with trunk sway when performing the tasks without vibrotactile biofeedback. Studies with larger sample sizes are needed.

A 2015 RCT by MacKay et al evaluated the addition of biofeedback to standard care in 40 patients with relapsing-remitting multiple sclerosis patients.23 The standard care psychosocial intervention consisted of relaxation, mindfulness, social support, and education. All patients attended 1-hour training and assessment sessions at weekly intervals. During the first session, all patients had training in mindfulness breathing exercises and progressive muscle relaxation techniques. Patients randomized to the biofeedback arm received additional instruction on use of biofeedback equipment for self-regulation. Following the 3 weekly sessions, patients were instructed to practice the exercises at home, with or without use of biofeedback equipment.
Outcomes included breathing rate and anxiety, depression, fatigue, and muscle tension measures. At the end of treatment, there were not statistically significant differences between groups in any outcomes. However, some variables were marginally significant. The difference between the intervention and control group in breathing rate was 3.06 (95% CI, -0.17 to 6.280; p=0.06) and the difference in muscle tension was -13.91 (95% CI, -30.06 to 2.25; p=0.09). Both groups had similar amounts of provider contact so nonspecific intervention effects were not a potential issue.

Section Summary: Multiple Sclerosis
Two RCTs using biofeedback techniques for the treatment of multiple sclerosis were identified. The sample sizes were small, with marginally significant differences between the biofeedback groups and control groups. Additional research with larger sample sizes is needed.

Orthostatic Hypotension in Patients With Spinal Cord Injury
Gillis et al (2008) conducted a systematic review to identify and describe the body of literature pertaining to nonpharmacologic management of orthostatic hypotension during the early rehabilitation of persons with spinal cord injury. Participants with any level or degree of completeness of spinal cord injury and any time elapsed since their injuries were included. Interventions must have measured at least systolic blood pressure and have induced orthostatic stress in a controlled manner and have attempted to control orthostatic hypotension during an orthostatic challenge. Thirteen studies (total N=138 patients) were included in the review. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified: application of compression and pressure to the abdominal region and/or legs (3 studies), upper body exercise (2 studies), functional electrical stimulation applied to the legs (6 studies), and biofeedback (2 studies). The 2 studies with 3 patients using biofeedback techniques reported an average of 39% increase in systolic blood pressure. The authors concluded that “…The clinical usefulness of compression/pressure, upper body exercise and biofeedback for treating OH [orthostatic hypotension] has not been proven.”

Section Summary: Orthostatic Hypotension in Patients With Spinal Cord Injury
A systematic review of nonpharmacologic management of orthostatic hypotension in patients with spinal cord injury identified 2 studies using biofeedback. While the studies showed that biofeedback effectively raised systolic blood pressure, these studies had a total of 3 patients. Additional research with larger sample sizes is needed.

Pain Management During Labor
In 2011 a Cochrane review was published that evaluated RCTs on biofeedback for managing pain during labor. The review identified 4 RCTs published between 1982 and 2000 with a total of 186 women. The studies were highly variable in terms of intervention modalities and outcomes measured, and thus findings were not pooled. In addition, the Cochrane review authors judged the trials to be at high risk of bias (eg, unclear description of blinding and randomization methods). Overall, the authors found little difference in reported outcomes (eg, rates of Cesarean section, pharmacologic pain relief in women receiving biofeedback compared with control interventions). Due to the small number of studies and small overall sample size, the evidence is insufficient to draw conclusions about the effectiveness of biofeedback in labor pain control.

Section Summary: Pain Management during Labor
A Cochrane review identified 4 RCTs using biofeedback techniques to manage pain during labor. Pooled estimates were not possible due to heterogeneity in techniques and outcomes.
Trials were also deemed high risk. A Cochrane review concluded that the evidence was insufficient to determine efficacy.

Posttraumatic Stress Disorder
The 2014 CADTH report on biofeedback for mood and anxiety disorders, previously discussed,\(^3\) included a systematic review of the literature on biofeedback for posttraumatic stress disorder (PTSD). One systematic review was identified; this study was published in 2014 by Wahbeh et al and addressed a variety of complementary and alternative medicine approaches to treating PTSD.\(^26\) Four of 33 studies that met selection criteria of the Wahbeh review addressed biofeedback. Among the biofeedback studies were 1 RCT, 1 nonrandomized trial, and 2 case series. The controlled trials either had mixed results or did not find a significant benefit of biofeedback. The reviewers gave the biofeedback evidence a grade C for unclear or conflicting scientific evidence.

Section Summary: Posttraumatic Stress Disorder
A systematic review of complementary and alternative medicine approaches to treating PTSD identified 4 studies (1 RCT, 1 nonrandomized trial, 2 case series) using biofeedback techniques. Results from the 4 studies were inconsistent. Larger controlled trials are needed.

Prevention of Preterm Birth
One small RCT was identified. In 2014, Siepmann et al published data on 48 women who had experienced threatened preterm labor between the 24th and 32nd gestational week.\(^27\) Twenty-four patients received 6 biofeedback sessions over 2 weeks, and the other 24 patients were in a usual care group. Preterm delivery occurred in 3 patients (13%) in the biofeedback group and 8 patients (33%) in the control group; the difference between groups was not statistically significant (\(p>0.05\)). Other gestational outcome data, such as the gestational duration and birthweight, also did not differ significantly between groups.

Section Summary: Prevention of Preterm Birth
A single RCT has been identified using biofeedback techniques to prevent preterm birth. There was no statistically significant difference between the biofeedback group and the control group in number of preterm deliveries or birthweight. Additional research is needed.

Raynaud Disease
A 2009 systematic review on complementary and alternative medicine in the treatment of Raynaud disease included an examination of the literature on biofeedback.\(^28\) Reviewers identified 5 trials using biofeedback techniques, and these reported a variety of outcomes. A pooled analysis of findings from 4 trials (total N=110) on the change in frequency of attacks favored the sham control group over the biofeedback group (weighted mean difference, -1.21; 95% CI, -1.68 to -0.73; \(p<0.000\)). Several trials had more than 2 arms; in the preceding analysis, only the arms comparing active and sham biofeedback were included.

The trial that was given the highest quality rating by the authors of the systematic review and had the largest sample size was the Raynaud’s Treatment Study, published in 2000.\(^29\) This was a randomized comparison of sustained-release nifedipine and thermal biofeedback in 313 patients with primary Raynaud disease. In addition to these two treatment groups, there were 2 control treatments: pill placebo and EMG biofeedback. EMG biofeedback was chosen as a control because it did not address the physiologic mechanism of Raynaud disease. The mean attack rate at 1 year, the primary study outcome, was 0.16 in the thermal biofeedback group, 0.23 in the EMG biofeedback group, 0.07 in the nifedipine group, and 0.21 in the placebo...
group. Nifedipine significantly reduced Raynaud attacks compared with placebo (p<0.002), but thermal feedback did not differ significantly from EMG biofeedback (0.37). There was not a significant difference in attack rates in the nifedipine and thermal biofeedback groups for the primary outcome (p=0.08). However, several secondary outcomes including all attacks and verified attacks at 2 months significantly favored nifedipine over thermal biofeedback.

**Section Summary: Raynaud Disease**
A systematic review identified 5 trials using biofeedback techniques for the treatment of Raynaud disease. A meta-analysis of 4 of the 5 trials showed a more favorable outcome for the patients in the sham control group.

**Sleep Bruxism**

**Systematic Reviews**
In 2013, Wang et al published a systematic review of randomized and non-RCTs on biofeedback treatment for sleep bruxism. The full text of 17 articles was reviewed and 7 studies with a total of 240 participants met the inclusion criteria. Studies were generally small; only 2 included more than 50 participants. Four studies used audio biofeedback, 2 used contingent electric stimulation, and 1 used visual biofeedback. Treatment duration ranged from 1 night to 6 weeks. In 4 of the studies, the duration of treatment was 2 weeks. Three of the studies were considered to be at moderate risk of bias and the other 4 were considered to be at high risk of bias. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Only 2 studies (total N=27) reported this outcome and had data suitable for meta-analysis. A pooled analysis did not find a statistically significant difference between the biofeedback and control groups (mean difference, -4.47; 95% CI, -12.33 to 3.38). Findings were not pooled for any other outcomes.

**Randomized Controlled Trials**
One of the larger RCTs (N=57) examined changes in sleep bruxism following treatment with a cognitive behavioral therapy program consisting of problem solving, progressive muscle relaxation, nocturnal biofeedback, and training of recreation and enjoyment. Similar improvements were observed for the occlusal splint group as for the multicomponent cognitive behavioral program. The effects of biofeedback were not isolated in this study, and thus conclusions cannot be drawn about its effectiveness compared with occlusal splinting.

In 2015, Sato et al published a study on the use of EMG biofeedback training for daytime clenching and its effect on sleep bruxism. Patients were monitored for 5 hours of daytime and night time, and were randomized to EMG biofeedback (n=7) or to a control group (n=5). Patients in the biofeedback group received a small auditory signal in the daytime when clenching activity was detected. There were significant decreases in EMG events during weeks 2 and 3 in the biofeedback group during daytime, and the decreases in events carried over into the night time. There were no decreases in EMG events in the control group.

**Section Summary: Sleep Bruxism**
A systematic review identified 17 studies using biofeedback techniques to treat sleep bruxism. Pooled analyses of 2 studies with the same outcome, number of sleep bruxism episodes per hour, did not find a significant difference between the biofeedback and control groups. Heterogeneity in biofeedback techniques, outcomes measured, and treatment duration did not allow for additional pooled analyses. An RCT published after the review tested electromyogram biofeedback reported significant reductions in clenching activity in the
biofeedback group, though the sample size was small. Additional research is needed with larger samples.

**Tinnitus**

An RCT by Weise et al investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany. Tinnitus patients (N=130) were randomly assigned to an intervention or a waiting-list control group. Treatment consisted of 12 sessions of a biofeedback-based behavioral intervention over a 3-month period. The primary outcome measures were global tinnitus annoyance and a daily rating of tinnitus disturbance measured by a Tinnitus Questionnaire (TQ) and a daily diary using visual analog scale scores. Patients in the waiting-list group participated in the treatment after the intervention group had completed the treatment. Results showed improvements in tinnitus annoyance, diary ratings of loudness, feelings of controllability, changes in coping cognitions, and changes in depressive symptoms in the control group. The TQ total score had a potential range of 0 to 84. The preassessment mean in the TQ total score was 54.7 and the postassessment mean was 32.5.

**Section Summary: Tinnitus**

A single RCT was identified that evaluated the use of a biofeedback technique to treat patients with tinnitus. While improvements were reported in the biofeedback group, additional research to confirm these results is needed.

**Summary of Evidence: Miscellaneous Indications**

For individuals with anxiety disorders who receive biofeedback, the evidence includes a systematic review and a randomized controlled trial (RCT) published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review on heart rate variability biofeedback and the RCT on diaphragmatic breathing relaxation reported positive effects of these treatments on anxiety. However, the trials had small sample sizes (median, 14 participants) and study quality was generally poor. Limitations of the studies included improper randomization, allocation concealment, and inadequate descriptions of randomization or missing data. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with asthma who receive biofeedback, the evidence includes 3 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCTs used 3 different biofeedback techniques, which provided patients with information on: carbon dioxide, heart rate, and respiratory sinus arrhythmia. While the trials reported improvements in each parameter on which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Bell palsy who receive biofeedback, the evidence includes 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCTs evaluated the efficacy of adding mirror and/or electromyography biofeedback to facial exercises. Sample sizes were small and there was heterogeneity across techniques used and length of treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with depression who receive biofeedback, the evidence includes an RCT. Relevant outcome are symptoms, functional outcomes, and quality of life. The RCT evaluated
the effect of neurofeedback training on the ability of patients to control emotional responses. While patients undergoing treatment were better able to decrease their emotional responses compared with controls, the sample size was small and additional research with larger populations is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with hypertension who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 36 RCTs, though sample sizes were small and overall study quality poor. A variety of biofeedback techniques were used: thermal, galvanized skin response, pulse wave velocity, and heart rate variability. Results across trials did not consistently show a benefit of biofeedback. Conclusions are limited due to the heterogeneity of the interventions and the generally poor quality of the trials. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews and RCTs published after the systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A systematic review identified 18 high-quality trials using the following biofeedback techniques: weight distribution on a platform sensor, muscle activity from electromyography, linear gait parameters, and joint angle from a goniometer. Feedback was visual, auditory, or both. Outcome measures were primarily assessments of motor activity in research settings, rather than clinical outcomes such as rate of falls or ability to perform activities of daily living. Pooled effects showed improvements in motor function in the short term. Evidence is limited due to the variability in type, duration, and intensity of the interventions and lack of long-term outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction after injury or lower-limb surgery who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 4 RCTs evaluating the use of electromyography biofeedback. Sample sizes were small, with half of the trials reported significant benefits of biofeedback and half no difference between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with multiple sclerosis who receive biofeedback, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One trial used vibrotactile biofeedback and the other provided patients with heart rate and muscle tension biofeedback. Sample sizes were small and trialists reported marginally significant differences between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a case report and a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The case report and case series provide information on 3 patients given visual and auditory feedback. Patients were able to raise their systolic blood pressure by an average of 39%. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals needing pain management during labor who receive biofeedback, the evidence includes 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. A
Cochrane review of the 4 trials assessed the trials as having a high risk of bias due to unclear descriptions of blinding and randomization methods. Due to the heterogeneity in biofeedback methods and outcomes measured, pooled analyses could not be performed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with posttraumatic stress disorder who receive biofeedback, the evidence includes an RCT, a nonrandomized study, and 2 case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The studies had small sample sizes and inconsistent results. A systematic review of the 4 studies rated the evidence a grade C for conflicting scientific evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. In the RCT, patients in the treatment group received heart rate variability biofeedback. Patients receiving the treatment experienced a decrease in perceived chronic stress, but there was no significant difference in number of preterm births, gestational duration, or birthweight. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Raynaud disease who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 5 RCTs using biofeedback techniques. Pooled analysis was performed on 4 of the 5 trials. Reduction in frequency of attacks was significantly lower in the sham-control group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with sleep bruxism who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 7 randomized and nonrandomized studies using biofeedback techniques. Studies were generally small, used different techniques, measured different outcomes, and were assessed as having either moderate or high risk of bias. Two studies reported number of bruxism episodes per hour and a pooled analysis of these studies showed no significant differences between biofeedback and control groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with tinnitus who receive biofeedback, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. Treatment consisted of a biofeedback-based behavioral intervention over a 3-month period. The treatment group experienced improvements in tinnitus annoyance, loudness ratings, controllability, coping cognitions, and depressive symptoms. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

Urinary Incontinence

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, Blue Cross Blue Shield Association received input 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.

Headache

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, Blue Cross Blue Shield Association received input through 3 physician specialty societies and 3 academic medical centers (4 inputs) regarding biofeedback for treatment of headache. Clinical input considered biofeedback to be a reliable and appropriate nonpharmacologic option for treatment of headaches.

PRACTICE GUIDELINES AND POSITION STATEMENTS

Urinary Incontinence

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.”

**American College of Physicians**
The American College of Physicians (2014) published clinical practice guidelines on nonsurgical management of urinary incontinence in women. 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 continence 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. 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. The guidelines made the following conclusions on the use of biofeedback for postprostatectomy 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**
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 biofeedback:

“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.”

**Constipation**

34
American Neurogastroenterology and Motility Society et al  
In 2015, the American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Motility jointly published consensus guidelines on biofeedback therapy for anorectal disorders. The guidelines included the following recommendations:

- “Biofeedback is recommended for the short-term and long-term treatment of constipation with dyssynergic defecation.”
- “Biofeedback therapy is recommended for the short-term and long-term treatment of fecal incontinence”
- “Biofeedback therapy is not recommended for the routine treatment of children with functional constipation, with or without overflow fecal incontinence.”

American Society of Colon and Rectal Surgeons  
In 2015, the American Society of Colon and Rectal Surgeons (ASCRS) updated its guidelines on treatment of fecal incontinence. The guidelines recommended that biofeedback be considered as an initial treatment for patients with fecal incontinence who have some preserved voluntary sphincter contraction ability.

In 2016, ASCRS published guidelines on the evaluation and management of constipation. The guidelines state that biofeedback therapy is a first-line treatment for symptomatic pelvic floor dyssynergia (strong recommendation, moderate quality of evidence).

American Gastroenterological Association  
In 2013, the American Gastroenterological Association updated its position statement on constipation. The statement included the following on biofeedback: “Pelvic floor retraining by biofeedback therapy rather than laxatives is recommended for defecatory disorders (Strong Recommendation, High-Quality Evidence).”

National Institute for Clinical Excellence  
In May 2010, the National Institute for Clinical Excellence (NICE) issued guidance on constipation in children and young people. The guidance indicated that biofeedback should not be used for ongoing treatment.

In June 2007, NICE issued guidance on fecal incontinence in adults; it stated the following on biofeedback: “The evidence we found did not show biofeedback to be more effective than standard care, exercises alone, or other conservative therapies. The limited number of studies and the small number of participants in each group of the studies make it difficult to come to any definitive conclusion about its effectiveness.”

American College of Gastroenterology  
In 2014, the American College of Gastroenterology published guidelines on the management of fecal incontinence. The guidelines indicated that pelvic floor rehabilitation techniques (eg, biofeedback, therapeutic exercises) are effective in patients with fecal incontinence who do not respond to conservative measures (strong recommendation, moderate quality of evidence).

Headache  
Association for Applied Psychophysiology and Biofeedback  
In 2013, the Association for Applied Psychophysiology and Biofeedback issued standards for performing biofeedback. The standards state that biofeedback for the treatment of migraine and tension headache has been validated as being safe and effective for these particular conditions.
conditions and that biofeedback is not used alone as a diagnostic tool or treatment; rather, it is an adjunctive tool to be used in combination with other standard interventions.

**National Institute of Neurologic Disorders and Stroke**
The National Institute of Neurologic Disorders and Stroke (2018) states that when headaches occur 3 or more times a month, preventive treatment is usually recommended:

“Drug therapy, biofeedback training, stress reduction, and elimination of certain foods from the diet are the most common methods of preventing and controlling migraine and other vascular headaches. Regular exercise, such as swimming or vigorous walking, can also reduce the frequency and severity of migraine headaches. Drug therapy for migraine is often combined with biofeedback and relaxation training.”

**American Academy of Family Physicians**
In 2000, the American Academy of Family Physicians published guidelines on preventive therapy for migraines, based on an evidence review by the U.S. Headache Consortium. The guidelines recommend relaxation training, thermal biofeedback combined with relaxation training, electromyographic (EMG) biofeedback, and cognitive-behavioral therapy (CBT) as treatment options for prevention of migraine (grade A recommendation). Relaxation techniques and biofeedback may be combined with preventative drug therapy to achieve additional clinical improvement (grade B recommendation). According to the guidelines, nonpharmacologic therapy may be well-suited for patients who have exhibited a poor tolerance or poor response to drug therapy, who have a medical contraindication to drug therapy, and who have a history of long-term, frequent or excessive use of analgesics or other acute medications. Nonpharmacologic intervention may also be useful in patients with significant stress or in patients who are pregnant, are planning to become pregnant, or are nursing.

**American Academy of Neurology**
The American Academy of Neurology’s recommendations for the evaluation and treatment of migraine headaches, published in 2000, states that behavioral and physical interventions are used for preventing migraine episodes rather than for alleviating symptoms once an attack has begun. Although these modalities may be effective as monotherapy, they are more commonly used in conjunction with pharmacologic management. Relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and CBT may be considered treatment options for prevention of migraine. Specific recommendations regarding which of these to use for specific patients cannot be made.

**European Federation of Neurological Societies**
In 2010, the European Federation of Neurological Societies gave an A-level recommendation for use of EMG biofeedback for the treatment of tension-type headache, based on the meta-analysis by Nestoriuc et al. The guidelines state that the aim of EMG biofeedback is to help the patient to recognize and control muscle tension by providing continuous feedback about muscle activity. Sessions typically include an adaptation phase, baseline phase, training phase, during which feedback is provided, and a self-control phase, during which the patient practices controlling muscle tension without the aid of feedback.

**Chronic Pain**

**American College of Occupational and Environmental Medicine**
A 2011 guideline by the American College of Occupational and Environmental Medicine recommended biofeedback for “select patients with chronic low back pain as a component (not
a separate procedure) of cognitive behavioral therapy (CBT) or as a procedure in the context of an interdisciplinary or functional rehabilitation program.” Biofeedback was not recommended for acute or subacute back pain.25

**American Society of Anesthesiologists et al**
A 2010 practice guideline by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine states that “Cognitive behavioral therapy, biofeedback, or relaxation training: These interventions may be used as part of a multimodal strategy for patients with low back pain, as well as for other chronic pain conditions.”26

### Miscellaneous Indications

**American Psychiatric Association**
The 2010 American Psychiatric Association guidelines on the treatment of patients with major depressive disorder did not list biofeedback as a potential treatment.34

The 2004 American Psychiatric Association guidelines on the treatment of patients with acute stress disorder and posttraumatic stress disorder mentioned that biofeedback may be used to augment relaxation techniques.35 The guidelines explained that biofeedback can provide patients with instantaneous feedback on physiological measures such as blood flow and muscle contraction, which enables patients to exert some degree of control over those measures to relieve tension and anxiety.

**American Academy of Sleep Medicine**
In 2008, an American Academy of Sleep Medicine special committee released a guideline on evaluation and management of chronic insomnia in adults.36 The guideline lists biofeedback as one of several behavioral or psychological therapies for chronic insomnia, as a potential method to reduce somatic arousal.

**Scottish Intercollegiate Guidelines Network**
The 2010 Scottish Intercollegiate Guidelines Network guideline on management of patients with stroke indicated that, based on evidence from 2 systematic reviews, “EMG [electromyographic] biofeedback is not recommended as a routine treatment for gait, balance or mobility problems after stroke.”37

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**Government Regulations**

**National:**

**NCD - BIOFEEDBACK Therapy (30.1),** this is a longstanding national coverage determination. The effective date of this version has not been posted.

**Indications and Limitations of Coverage**
Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific, muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm or weakness, and more conventional treatments (heat, cold, massage, exercise, and support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.
Indications and Limitations of Coverage
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.

Local:
Wisconsin Physicians Service Insurance Corporation
Local Coverage Determination, Biofeedback (L31070) - Retired

Indications and Limitations of Coverage and/or Medical Necessity

Biofeedback training is a type of behavioral technique by which information about a normally unconscious physiologic process is presented to the patient and is demonstrated by a signal to educate the patient for an optimal muscle response. Retraining typically includes a process by which the patient is evaluated in the office setting and taught how to utilize the affected muscle group therapeutically. The muscle group involved is monitored with a device where the patient can observe, through visual or auditory means, the muscle group movements. Where there is abnormal or absent muscle movements, the patient can be reinforced with observed changes with optimal muscle movements. The patient will then practice the learned techniques. The patient will continue to practice at home (or other non-office setting) the optimal muscle movements utilizing the training guide.

A. Biofeedback training is typically performed in situations where a patient has had other therapies that have been unsuccessful or contraindicated. Other therapies include, but are not limited to,
   1. Pharmacological treatments,
   2. Physical therapy treatment, and
   3. Exercise training.
   4. Occupational Therapy.
   5. Speech Therapy

B. Biofeedback training has been proven successful when all of the following criteria exist:
   1. The patient is motivated to actively participate in the treatment plan, including being responsive to the care plan requirements (e.g., practice and follow-through at home);
2. The patient must be capable of participating in the treatment plan (physically as well as intellectually);
3. The patient’s condition is appropriately treated with biofeedback (e.g., pathology does not exist preventing success of the training).

C. Medicare coverage will be allowed for medically necessary biofeedback training when performed with the continuous presence of a physician or by a qualified non-physician practitioner. Continuous presence requires one-on-one face-to-face involvement with the patient and practitioner during training.

D. There should be a plan of care certified by the Medicare attending/ordering physician/provider, which contain the goals of therapy, the exercise prescription, and measurable objectives.

E. Biofeedback Training (CPT code 90901) is considered medically necessary when other treatments have failed or are contraindicated and it is performed for one of the indications listed in this LCD.

F. Biofeedback training anorectal, including EMG and/or manometry (CPT code 90911) is covered for anal muscle abnormalities of spasticity, incapacitating muscle spasm, dyssynergic, and/or muscle weakness.
   a. Anal spasms (ICD-9 code 564.6)
   b. Detrusor sphincter dyssnergia (596.55)
   c. Fecal incontinence (ICD-9 code 787.60-787.63)
   d. Slow Transit Constipation (ICD-9 564.01)
   e. Outlet Dysfunction Constipation (ICD-9 564.02)

G. Biofeedback for pelvic floor retraining for urinary incontinence (90911) is covered if performed with the aid of EMG and/or electrical stimulation techniques when other treatments have not been effective or contraindicated, for the following conditions:
   a. Intrinsic urethral sphincter deficiency (ICD-9 code 599.82)
   b. Stress incontinence, female (ICD-9 codes 625.6)
   c. Urinary incontinence, unspecified (ICD-9 codes 788.30)
   d. Urge Incontinence (ICD-9 code 788.31)
   e. Stress incontinence, male (ICD-9 code 788.32)
   f. Mixed incontinence (ICD-9 code 788.33)

H. Muscle Spasms (728.85) is covered only when the medical record contains documentation that indicates the site and that the spasms are incapacitating.

**Michigan Department of Health and Human Services (MDHHS):**
Per the Michigan Medicaid Provider Manual, version date July 2018, biofeedback is a noncovered service.

*The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.*)
Related Policies

- Neurofeedback
- Psychophysiological Therapy (Biofeedback) for the Treatment of TMJ Disorders (Retired)
- Psychophysiological Therapy for Treatment of Nocturnal Enuresis

References

Urinary Incontinence


Voiding Dysfunction in Children

Fecal Incontinence and Constipation

22. Blue Cross Blue Shield Association, "Biofeedback as a Treatment of Fecal Incontinence," Medical Policy Reference Manual, Policy # 2.01.64, original date 12/17/03, last review date 11/10/16.

**Headache**


**Chronic Pain**


Miscellaneous Indications


Government Regulations
3. Wisconsin Physicians Service (WPS), "Biofeedback," WPS Local Medical Review Policy, L31070, contractor determination number PHY-066, original effective date 4/15/11, original determination ending date 5/1/12.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/29/18, the date the research was completed.
<table>
<thead>
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<th>Policy Effective Date</th>
<th>BCBSM Signature Date</th>
<th>BCN Signature Date</th>
<th>Comments</th>
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<td>10/14/04</td>
<td>Joint policy established</td>
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<td>Routine maintenance; added chronic constipation to covered conditions</td>
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Next Review Date: 4th Qtr, 2019
BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BIOFEEDBACK

I. Coverage Determination:

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<th>Plan Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>Commercial HMO</td>
<td>Covered; criteria applies.</td>
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<td>(includes Self-Funded groups unless otherwise specified)</td>
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<tr>
<td>BCNA (Medicare Advantage)</td>
<td>See Government Regulations section. If there is no NCD or LCD, medical policy criteria apply.</td>
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<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service. <strong>Exception:</strong> If BCN65 member has an “exact-fill” option, BCN may cover the service even if Medicare does not.</td>
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II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.