Kansas City
An Independent Licensee of the Blue Cross and Blue Shield Association

Biofeedback for Miscellaneous Indications

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Biofeedback for Miscellaneous Indications. This is considered investigational.

Note: This is a type of treatment that may be excluded in some contracts. Verify benefits prior to review for Medical Necessity.

When Policy Topic is covered

n/a

When Policy Topic is not covered

Biofeedback is considered **investigational** as a treatment of the following miscellaneous conditions:

- anxiety disorders
- asthma
- Bell palsy
- depression
- hypertension
- insomnia
- movement disorders, such as motor function after stroke, injury, or lower-limb surgery
- multiple sclerosis
- orthostatic hypotension in patients with spinal cord injury
- pain management during labor
- posttraumatic stress disorder
- prevention of preterm birth
- Raynaud disease
- sleep bruxism
- tinnitus

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: ▪ With anxiety disorders	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With asthma	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With Bell palsy	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With depression	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With hypertension	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With motor dysfunction after stroke	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With motor dysfunction after injury or lower limb surgery	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With multiple sclerosis	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With orthostatic hypotension due to spinal cord injury	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ Who need pain management during labor	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With posttraumatic stress disorder	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ Who are susceptible to	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes

preterm birth			▪ Quality of life
Individuals: ▪ With Raynaud disease	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With sleep bruxism	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life
Individuals: ▪ With tinnitus	Interventions of interest are: ▪ Biofeedback	Comparators of interest are: ▪ Standard care	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. This policy focuses on the use of biofeedback for treating miscellaneous indications. Specifically, these are indications other than urinary and fecal incontinence, headache, and chronic pain.

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 outcomes 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.

Background

Biofeedback is a technique intended to teach patients self-regulation of certain unconscious or involuntary physiologic processes. Biofeedback equipment takes physiological signals and creates output that can be given to patients. 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 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. This policy focuses on the use of biofeedback for the treatment of hypertension, anxiety, insomnia, asthma, and other miscellaneous applications (ie, conditions not addressed in other policies on biofeedback).

In addition, this evidence review focuses on biofeedback devices that measure and provide information on the physiologic processes such as heart rate, muscle tension, skin temperature, and blood flow. Electroencephalographic biofeedback, also called neurofeedback, which measures brainwave activity, is addressed elsewhere.

REGULATORY STATUS

A large number of biofeedback devices have been cleared through the U.S. Food and Drug Administration’s 510(k) process since 1976.

Rationale

This evidence review was created and July 1997 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through June 22, 2017.

This review was informed by a 1995 TEC Assessment, which 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.(1)

Psychological treatments involve both nonspecific and specific therapeutic effects. Nonspecific effects, sometimes called placebo effects, occur as a result of therapist contact, positive expectancies on the part of the subject and the therapist, and other beneficial effects that occur as a result of being a patient in a therapeutic environment. Specific effects are those that occur only because of the active treatment, above any nonspecific effects that may be present. The literature review focuses on identifying evidence that isolates the specific effect of biofeedback, apart from the nonspecific placebo effects. Because 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 difficult. 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. The following is a summary of the key literature to date.

ANXIETY DISORDERS

Systematic Reviews

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.(2) 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.(3) 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.(4) 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.(5) 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)(6); HRV using a physiograph (N=94)(7); and respiratory sinus arrhythmia by ECG feedback and muscle tension by electromyography (N=17).(8) 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 on which the patients received biofeedback, but those improvements did not impact clinical benefits such as decreased medication use or increased FEV_1.

BELL PALSY
In 2008, Cardoso et al published a systematic review of studies on the effects of facial exercises on symptoms of Bell palsy.(9) 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 vs control (n=50), mirror biofeedback exercise versus control (n=27), "small" mirror movements vs conventional neuromuscular retraining (n=10), and EMG biofeedback plus mirror training vs mirror training alone. The treatment length varied from 1 to 12 months. Reviewers 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 used and length of treatments.

DEPRESSION

The 2014 Canadian Agency for Drugs and Technology in Health report on biofeedback for mood and anxiety disorders (previously discussed in the Anxiety section),[3] included a systematic review of the literature on biofeedback for depression. Other than 2 dissertations using HRV biofeedback, no health technology assessments, systematic reviews, meta-analyses, RCTs, or nonrandomized studies evaluating biofeedback for the treatment of depression were identified.

Section Summary: Depression
A 2014 Canadian agency report identified 2 dissertations using HRV biofeedback to treat depression. No peer-reviewed literature has been identified since the report that has evaluated biofeedback techniques to treat depression.

HYPERTENSION

Systematic Reviews

A systematic review of studies on biofeedback for hypertension was published by Greenhalgh et al in 2009.[10] 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. Thirty-six trials (total N=1660 patients) 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 HRV; some trials used more than 1 modality. Twenty studies evaluated biofeedback alone, 15 evaluated biofeedback combined with another intervention, and one had multiple arms and evaluated both types of interventions; only 4 trials included a sham biofeedback comparison group. Reviewers 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 with 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 could not be determined from this analysis. Only 1 trial compared a biofeedback combination intervention with sham biofeedback, and it 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 them 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 have tended to have relatively small sample sizes, and only small RCTs were identified in literature search updates.[12,13] Recent systematic reviews and RCTs not included in the systematic reviews are discussed below.

Systematic Reviews

In 2017, Stanton et al updated a 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.[14] 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 standardized mean difference of the short-term effect of biofeedback from 17 trials (n=417) was significant (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.[15] 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.[16] Although the review was not limited to studies on motor function after stroke, more than half of the studies included older adults poststroke. For review inclusion, studies had to include a control group of patients who did not receive biofeedback and to assess at least 1 objective outcome measure. A total of 21 studies, including 17 RCTs, met selection criteria. Twelve (57%) of the 21 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, ranging from 5 to 30 patients. The added benefit of using biofeedback could be evaluated in 13 (62%) of 21 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 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 them 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.[17] 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 scores improved significantly more in the patients receiving EMG biofeedback. However, there was not a significant difference in FIM score improvement between groups.

In 2016, 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.[18] 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 an area of center of pressure). Comparison statistics were calculated for pre- and posttraining

results, and between treatment groups. Both outcomes significantly improved in the biofeedback group but not 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.[19] 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 the center of pressure and approximate entropy. Both groups experienced improvements in postural control, with no significant differences between rehabilitation methods.

Section Summary: Motor Dysfunction 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 activities of daily living or the rate of falls, is unknown. In addition, few studies have reported long-term outcomes. Due to these limitations, the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from the evidence published to date.

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.[20] 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, while the others did not. 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 for trunk sway on balance control in patients with multiple sclerosis.[21] 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 differed significantly 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.[22] The standard of 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 the use of biofeedback equipment for self-regulation. Following the 3 weekly sessions, patients were instructed to practice the exercises at home, with or without the use of biofeedback equipment. Outcomes included breathing rate and anxiety, depression, fatigue, and muscle tension measures. At the end of treatment, there were no statistically significant differences between groups in any outcomes. However, some variables were marginally significant. The difference between the intervention group and the control group in breathing rate was 3.06 beats per minute (95% CI, -0.17 to 6.28 beats per minute; p=0.06) and the difference in muscle tension was -13.91 μV (95% CI, -30.06 to 2.25 μV; p=0.09). Both groups had similar amounts of provider contact, so nonspecific intervention effects were not an 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.(24) 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 evaluated RCTs on biofeedback for managing pain during labor.[24] Reviewers identified 4 RCTs published between 1982 and 2000 (total N=186 women). The studies were highly variable in terms of intervention modalities and outcomes measured, and thus findings were not pooled. In addition, reviewers judged the trials to be at high risk of bias (eg, unclear description of blinding and randomization methods). Overall, they found little difference in reported outcomes (eg, rates of Cesarean section, pharmacologic pain relief in women receiving biofeedback vs control interventions). Due to the small number of studies and small pooled sample size, the evidence did not support drawing 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.

POSTTRAUMATIC STRESS DISORDER

The 2014 Canadian Agency for Drugs and Technology in Health 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; it was published in 2014 by Wahbeh et al and addressed various complementary and alternative medicine approaches to treating PTSD.[25] 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. 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 using biofeedback techniques. Results from these 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.[26] 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 (13%) patients in the biofeedback group and 8 (33%) patients in the control group; the difference between groups was not statistically significant (p>0.05). Other gestational outcomes 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 literature on biofeedback.[27] Reviewers identified 5 trials using biofeedback techniques, and they reported a variety of outcomes. A pooled analysis of findings from 4 trials (n=110 patients) on the change in frequency of attacks (typically extremities feel cold and numb) 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 with sham biofeedback were included.

The trial that was given the highest quality rating by the systematic reviewers and with the largest sample size was the Raynaud's Treatment Study, published in 2000.[28] This was a randomized comparison of sustained-release nifedipine and thermal biofeedback in 313 patients with primary Raynaud disease. In addition to these 2 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 physiological 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).

Section Summary: Reynaud Disease
A systematic review identified 5 trials using biofeedback techniques for the treatment of Raynaud disease. A meta-analysis of four of these trials showed more favorable outcomes for the patients in the sham-control group.

SLEEP BRUXISM

Systematic Reviews
In 2014, Wang et al published a systematic review of RCTs and non-RCTs on biofeedback treatment for sleep bruxism.[29] Seventeen articles was reviewed, and 7 studies with (total N=240 participants) met the inclusion criteria. Studies were generally small; only 2 included more than 50 participants. Four studies used

audio biofeedback, two used contingent electric stimulation, and one used visual biofeedback. Treatment duration ranged from 1 night to 6 weeks. In 4 studies, the duration of treatment was 2 weeks. Three of the studies were considered at moderate risk of bias, and the other four were considered 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 (n=27 patients) 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.[30] Similar levels of improvements were observed for the occlusal splint group and 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.[31] 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 the 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

A 2009 RCT by Weise et al investigated the efficacy of a biofeedback-based cognitive behavioral treatment for tinnitus in Germany.[32] Tinnitus patients (N=130) were randomized to an intervention group 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) 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 reductions in tinnitus annoyance, diary ratings of loudness, improvements in feelings of controllability, changes in coping cognitions, and changes in depressive symptoms in the biofeedback group. The Tinnitus Questionnaire total score has a potential range of 0 to 84. The preassessment mean in the Tinnitus Questionnaire 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 would be needed to confirm these results.

Other Indications
No current evidence was identified for the use of biofeedback techniques to treat other indications including insomnia.

SUMMARY OF EVIDENCE

For individuals with anxiety disorders 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 on heart rate variability biofeedback and the RCT on diaphragmatic breathing relaxation reported the positive effects of these treatments on anxiety. However, the trials had small sample sizes (median, 14 participants) and study quality was generally poor. Additional limitations 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. Each RCTs used a different biofeedback technique, 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 outcomes 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. Various 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 were limited due to the heterogeneity across 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. The 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 lower-limb injury or 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 reporting significant benefits of biofeedback and the other half reporting 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 collectively provided 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 who need 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 assessed the four selected 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 the 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 four of these 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 the number of bruxism episodes per hour and a pooled analysis of these studies showed no significant differences between biofeedback groups 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 single 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. Additional studies are needed to confirm the results of this single trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

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.[33]

The 2004 Association guidelines on the treatment of patients with acute stress disorder and posttraumatic stress disorder mentioned use of biofeedback to augment relaxation techniques.[34] The guidelines suggested that biofeedback could provide patients with instantaneous feedback on physiological measures such as blood flow and muscle contraction, which would enable patients to exert some degree of control over those measures to relieve tension and anxiety.

American Academy of Sleep Medicine

In 2008, the American Academy of Sleep Medicine released guidelines on the evaluation and management of chronic insomnia in adults.[35] The guidelines listed biofeedback as one of several behavioral or psychological therapies to reduce chronic somatic arousal.

Scottish Intercollegiate Guidelines Network

The 2010 Scottish Intercollegiate Guidelines Network guidelines on the 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."[36]

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

No U.S. Preventive Services Task Force recommendations for use of biofeedback have been identified.

MEDICARE NATIONAL COVERAGE

National Coverage Determination for Biofeedback Therapy (30.1) stated:

> "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, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions."[37]

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02119936	Feasibility of Heart Rate Variability Feedback as a Stress Reduction Tool for Hospitalized Pregnant Women	30	Dec 2016 (ongoing)
NCT03039231	Investigation of the Freespira Breathing System in the Treatment of Post-traumatic Stress Disorder	55	Jun 2018
NCT02667392	Biofeedback to Increase Propulsion During Walking after Stroke	30	Jul 2018
NCT02998502	Efficacy of a Biofeedback Breathing System for Anxiety and Panic Disorders	60	Sep 2018
NCT02237885	Pain Management Using Mobile Technology in Veterans with Post-traumatic Stress Disorder and Traumatic Brain Injury	100	Oct 2018
NCT03030326	Biofeedback for Asthma Comorbid with Anxiety or Depression	20	Dec 2020

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Billing Coding/Physician Documentation Information

90875 Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes

90876 Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes

90901 Biofeedback training by any modality

E0746 Electromyography (EMG), biofeedback device

Additional Policy Key Words

N/A

Policy Implementation/Update Information

10/1/15 New Policy. Considered Investigational.

10/1/16 No policy statement changes.

10/1/17 Minor edits to the Policy section; statement otherwise unchanged.

10/1/18 No policy statement changes.