

2.01.53 Biofeedback for Miscellaneous Indications			
Original Policy Date:	October 1, 2010	Effective Date:	February 1, 2020
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Policy Statement

Biofeedback is considered **investigational** as a treatment of **any** 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.

Policy Guidelines

Coding

Biofeedback for miscellaneous indications may be billed with the following CPT and HCPCS codes:

- **90901**: Biofeedback training by any modality
- **E0746**: Electromyography (EMG), biofeedback device

Note: Some Blue Shield of California (BSC) plans exclude coverage of biofeedback. Please check benefit plan descriptions for details. Biofeedback may be covered for some indications such as migraine headaches and constipation related to dyssynergia (see Related Policies section below).

Biofeedback devices: Unsupervised home use of a biofeedback device has not been well studied, and further is excluded from coverage per Blue Shield Evidence of Coverage (EOC) General Exclusions and Limitations.

Description

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes that are otherwise impossible or extremely difficult to control. This review focuses on the use of biofeedback for treating miscellaneous indications-specifically, indications other than urinary and fecal incontinence, headache, and chronic pain.

Related Policies

- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback as a Treatment of Headache
- Biofeedback as a Treatment of Urinary Incontinence in Adults

- Neurofeedback
- Treatment of Tinnitus

Benefit Application

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

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

Regulatory Status

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

Rationale

Background

Biofeedback is a technique intended to teach patients the self-regulation of certain unconscious or involuntary physiologic processes. Biofeedback equipment converts physiological signals into outputs 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 (e.g., visual, auditory) depends on the nature of the disease or disorder being treated. This evidence review focuses on the use of biofeedback for the treatment of hypertension, anxiety, insomnia, asthma, movement disorders (e.g., motor function after stroke, injury, or lower-limb surgery), and other applications (i.e., conditions not addressed in other evidence reviews on biofeedback).

In addition, this evidence review focuses on biofeedback devices that measure and provide information on physiologic processes such as heart rate, muscle tension, skin temperature, and blood flow. Electroencephalographic biofeedback, also called neurofeedback, which measures brainwave activity, is addressed in Blue Shield of California Medical Policy: Neurofeedback.

Literature Review

This review was informed by a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (1995), which concluded that the evidence was insufficient to demonstrate the effectiveness of biofeedback for the treatment of 9 conditions: anxiety disorders, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia.¹

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that

condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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. This 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 an 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.

Anxiety Disorders

Clinical Context and Therapy Purpose

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with anxiety disorders.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with anxiety disorders?

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

Patients

The relevant population of interest are individuals with anxiety disorders.

Interventions

The therapy being considered is biofeedback. Patients with anxiety disorders are actively managed by psychologists and other mental health professionals in an outpatient setting.

Comparators

The following practice is currently being used to treat anxiety disorders: standard of care. Patients with anxiety disorders are actively managed by psychologists and other mental health professionals in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at eight weeks is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Goessl et al (2017) published a meta-analysis on the effect of heart rate variability (HRV) biofeedback (HRVB) 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 risk of bias tool was used to assess study quality. Many studies had high or unclear risk of bias due to the following factors: inadequate randomization descriptions, improper randomization, undescribed allocation concealment, and missing data that was either not described or mishandled; 13 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.

The Canadian Agency for Drugs and Technology in Health (2014) published a rapid response report on biofeedback for treating mood and anxiety disorders.³ This 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

Chen et al (2017) published an RCT comparing diaphragmatic breathing relaxation (DBR) with routine respiration activities in the treatment of 46 patients with anxiety.⁴ DBR is a technique that uses diaphragm muscle contractions to force air downward into the body, increasing diaphragm length and breathing efficiency. Outcomes were anxiety level, measured by the Beck Anxiety Inventory, and four physiological measures (skin conductivity, peripheral blood flow, heart rate, breathing rate). All patients participated in an individualized 8-week course in breathing relaxation, but only 30 completed it. 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 eight weeks, the DBR group experienced statistically significant decreases in Beck Anxiety Inventory scores compared with baseline, while the control group did not. The DBR group also experienced significant improvements in all four physiological measurements, while the control group did not.

Section Summary: Anxiety Disorders

Two systematic reviews on HRVB found that biofeedback had a positive effect on anxiety levels, though the studies had small sample sizes and, in general, were of poor quality. An RCT evaluating DBR 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

Clinical Context and Therapy Purpose

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with asthma.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with asthma?

The following PICO's were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with asthma.

Interventions

The therapy being considered is biofeedback. Patients with asthma are actively managed by primary care providers in an outpatient setting.

Comparators

The following practice is currently being used to treat asthma: standard of care. Patients with asthma are actively managed by primary care providers in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Though not completely standardized, follow-up for asthma symptoms would typically occur in the months to years after starting treatment.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

Yorke et al (2015) published a systematic review 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 groups: relaxation-based therapies (n=9 studies); cognitive-behavioral therapies (n=5 studies); biofeedback techniques (n=3 studies); and mindfulness (n=1 study). Five studies incorporated multicomponent interventions. The 3 biofeedback RCTs used different techniques: exhaled carbon dioxide capnography (pooled n=12)⁶; HRV using a physiograph (pooled n=94 patients)⁷; and respiratory sinus arrhythmia by electrocardiographic feedback and muscle tension by electromyography (EMG; pooled n=17 patients).⁸ Common outcomes in the three trials 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 were found and medication use decreased in only one trial. Reviewers concluded that larger sample sizes were needed to demonstrate effects and that, differences between treatment groups did not translate into meaningful clinical benefits.

Randomized Controlled Trials

Taghizadeh et al (2019) hypothesized that HRVB could decrease vulnerability to stress-induced pulmonary impairment in patients with asthma.⁹ Twenty-two healthy women and 22 women with asthma participated in the study. Eleven participants from each group were randomly allocated to either HRVB or a control group. Using spirometry, all participants' lung function was tested at baseline and after performing the Stroop color-word task. Before the 10-minute Stroop test, each group underwent 20 minutes of either HRVB (treatment group) or maintained a state of relaxed alertness while listening to classical music (control group), after which the groups had similar stress levels as self-reported on a visual analog scale. After the test, all participants again rated their stress levels. All four groups were statistically significantly stressed ($p < .001$). Although the healthy group who underwent HRVB reported significantly less stress than the healthy control group ($p = .034$), the participants with asthma did not experience this effect. In fact, larger stress-induced HRV changes suggested an exaggerated response in asthmatic participants compared to the healthy ones. However, spirometry parameters, which were monitored

throughout the experimental procedures, showed that HRVB had a protective effect on the participants with asthma as well as enhanced the level of forced expiratory volume percent ($p = 0.002$) and forced vital capacity percent ($p < 0.001$) as compared to baseline. The authors concluded that HRVB is a promising protective approach to aid lung function and reduce asthma exacerbation caused by stress. Some limitations of the study include using only the Stroop test to induced stress, measuring stress on a subjective visual analog scale, and including only female participants.

Lehrer et al (2018) examined the efficacy and safety of HRVB on asthma to determine if the treatment could substitute for the controller or rescue medication and whether HRVB controls airway inflammation.¹⁰ In the 2-center trial, 68 paid steroid-naïve volunteers with mild-to-moderate asthma received 3 months of HRVB or a comparison condition consisting of electroencephalography alpha biofeedback with relaxing music and relaxed paced breathing. Both treatment conditions showed similar significant improvements on the methacholine challenge test, asthma symptoms, and asthma QOL, and the administration of albuterol after biofeedback sessions produced a large improvement in pulmonary function test results. Trial data would suggest that HRVB not be considered as an alternative to asthma controller medications.

Section Summary: Asthma

A recent systematic review identified three RCTs using three biofeedback techniques, and a recent clinical trial examined two biofeedback techniques to treat asthma. These reported minor improvements in patients receiving biofeedback, but those improvements did not impact clinical benefits such as decreased medication use or increased forced expiratory volume in 1 second. Two additional RCTs were identified. The results of one led to the conclusion that HRVB has promise as a protective approach to aiding lung function and reducing stress-induced asthma exacerbation. Results from the other RCT suggested that HRVB is not an effective alternative to asthma control medications.

Bell Palsy

Clinical Context and Therapy Purpose

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with Bell palsy.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with Bell palsy?

The following PICO's were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with Bell palsy.

Interventions

The therapy being considered is biofeedback. Patients with Bell palsy are actively managed by physical therapists and neurologists in an outpatient setting.

Comparators

The following practice is currently being used to treat Bell palsy: standard of care. Patients with Bell palsy are actively managed by physical therapists and neurologists in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Treatment and follow-up over 1 to 12 months are of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

Cardoso et al (2008) published a systematic review on the effects of facial exercises on symptoms of Bell palsy.¹¹ Studies including patients with unilateral idiopathic facial palsy treated with facial exercises associated with mirror and/or EMG biofeedback were selected. Four studies (total n=132 patients) met the eligibility criteria. The studies described mime therapy vs control (n=50 patients), mirror biofeedback exercise vs control (n=27 patients), "small" mirror movements vs conventional neuromuscular retraining (n=10 patients), and EMG biofeedback plus mirror training vs mirror training alone. The treatment length varied from 1 to 12 months. Reviewers concluded that, given the paucity of RCTs, the current evidence does not support the use of biofeedback to treat this population.

Section Summary: Bell Palsy

A systematic review identified four studies using four biofeedback techniques to treat Bell palsy. The sample sizes were small, and there was heterogeneity in the techniques used and length of treatments.

Depression**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with depression.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with depression?

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

Patients

The relevant population of interest are individuals with depression.

Interventions

The therapy being considered is biofeedback. Patients with depression are actively managed by psychiatrists, psychologists and other mental health professionals in an outpatient setting.

Comparators

The following practice is currently being used to treat depression: standard of care. Patients with depression are actively managed by psychiatrists, psychologists and other mental health professionals in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Though not completely standardized, follow-up for depression symptoms would typically occur in the months to years after starting treatment.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

The Canadian Agency for Drugs and Technology in Health (2014) 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 two 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 Canadian agency (2014) report only identified 2 dissertations using HRV biofeedback to treat depression.

Hypertension**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with hypertension.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with hypertension?

The following PICO's were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with hypertension.

Interventions

The therapy being considered is biofeedback. Patients with hypertension are actively managed by primary care providers, cardiologists, and nephrologists in an outpatient setting.

Comparators

The following practice is currently being used to treat hypertension: standard of care. Patients with hypertension are actively managed by primary care providers, cardiologists, and nephrologists in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at six months is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

A systematic review of studies on biofeedback for hypertension was published by Greenhalgh et al (2009).¹² 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 were small; only 4 included more than 100 patients. All were single-center, and most were conducted in the U. S. Trials used a variety of biofeedback techniques including thermal biofeedback, galvanized skin response, pulse wave velocity, and HRV; some used more than one 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. 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 one of five 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 one trial

compared a biofeedback combination intervention with sham biofeedback, and it did not find a significant difference in the efficacy of the two interventions. Four studies on biofeedback alone and another four on a combined biofeedback intervention reported data beyond six 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 in patients with prehypertension or stage I hypertension.¹³ 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 the control group received pseudo-feedback signals (n=28). Outcomes were systolic and diastolic blood pressure, measured at baseline and one and eight weeks after training. Both groups significantly decreased blood pressure following training. The decreases were equal in magnitude, suggesting that blood pressure self-regulation training could effectively lower blood pressure, regardless of the type of feedback signal.

Section Summary: Hypertension

Although a large number of RCTs have suggested that biofeedback has efficacy in the treatment of hypertension, the evidence is insufficient due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of trials, and heterogeneity across interventions used.

Motor Dysfunction After Stroke

Clinical Context and Therapy Purpose

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with motor dysfunction after stroke.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with a movement disorder such as motor dysfunction after stroke?

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

Patients

The relevant population of interest are individuals with motor dysfunction after stroke.

Interventions

The therapy being considered is biofeedback. Patients with motor dysfunction after stroke are actively managed by physical therapists and primary care providers in an outpatient setting.

Comparators

The following practice is currently being used to treat stroke-related motor dysfunction: standard of care. Patients with motor dysfunction after stroke are actively managed by physical therapists and primary care providers in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Though not completely standardized, follow-up for motor dysfunction after stroke would typically occur in the months to years after starting treatment.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

Stanton et al (2017) updated a systematic review and meta-analysis published in 2011, which evaluated the effect of biofeedback on lower-limb activities in patients who have had a stroke.^{14,15} Only high-quality RCTs or quasi-RCTs with Physiotherapy Evidence Database scores greater than four were included. Training activities were walking (nine trials), standing (eight trials), and standing up (one trial). 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 seven trials, auditory in seven trials, and a combination of visual and auditory in four trials. The 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 four trials provided that information.

A systematic review by Zijlstra et al (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 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 one objective outcome measure. 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 than with control interventions. However, the outcomes assessed were generally not clinical outcomes but laboratory-based measures related to executing a task (e.g., moving from sitting to standing) in a laboratory setting and platform-based measures of postural sway. Only three studies reported long-term outcomes, and none of them reported a significant effect of biofeedback.

Table 1 summarizes the characteristics of selected systematic reviews.

Table 1. Characteristics of the Systematic Review

Study	Dates	Trials	Participants ¹	N (Range)	Design	Duration
Stanton et al (2017) ¹⁴	To 2015	18	Lower-limb motor function loss poststroke	429 (12-50)	RCTs	NR
Zijlstra et al (2010) ¹⁶	1993-2012	21	Patients >60 y receiving biofeedback to improve motor function	NR (5-30)	17 RCTs, 4 other	NR

NR: not reported; RCT: randomized controlled trials.

Other systematic reviews have noted that RCTs have tended to have relatively small sample sizes.^{17,18}

Randomized Controlled Trials

Kim (2017) published an RCT on the effect of EMG on upper-extremity function in patients who have had a stroke.¹⁹ Patients were randomized to traditional rehabilitation therapy (n=15) or traditional rehabilitation therapy plus EMG biofeedback training (n=15). The upper-limb function was measured by the Fugl-Meyer Assessment and the Manual Function Test, and activities of daily living were measured using the Functional Independence Measure instrument. Both Fugl-Meyer Assessment and the Manual Function Test scores improved significantly more in patients receiving EMG biofeedback. However, there was no significant difference in Functional Independence Measure score improvement between groups.

Yang (2016) 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.²⁰ 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 the center of pressure). Comparison statistics were calculated for pre- and post-training results, and between treatment groups. The biofeedback group significantly improved on both outcomes compared with the control group.

Ghomashchi (2016) published an RCT that evaluated the effect of visual biofeedback on postural balance disorders in patients who have had a stroke.²¹ 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.

Case Series

In a case series, Pellegrino et al (2017) tested the use of visual biofeedback in reducing postural control deficits on 11 chronic stroke survivors.²² Each participant was assessed using the Berg Balance Scale, the Trunk Impairment Scale, and the Nottingham Sensory Assessment Scale for trial inclusion. The test method involved seating each participant on a custom-built force platform and mapping their initial center of pressure positions. The trial had four phases: familiarization, training, and pre- and post-training tests. After familiarization and training, subjects were tested to observe if and to what extent they could transfer performance improvement obtained with visual feedback training to the conditions where they have to move (1) without visual feedback, (2) in different directions, and (3) respond to different displacement amplitudes. The study found that most stroke survivors were able to perform the required task and improve task performance during the training phase when provided visual feedback, however, without visual feedback, most showed no improvement in pretraining performance. The authors concluded that postural training based exclusively on continuous visual feedback provided limited benefits. The small sample size and design limit conclusions to be drawn from the study results.

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 by type, duration, and intensity of interventions. In addition, the outcome measures used were primarily assessments of motor activity 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 current evidence.

Motor Dysfunction after Lower-Limb Injury or Surgery

Clinical Context and Therapy Purpose

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with motor dysfunction after lower-limb injury or surgery.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with motor dysfunction after lower-limb injury or surgery?

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

Patients

The relevant population of interest are individuals with motor dysfunction after lower-limb injury or surgery.

Interventions

The therapy being considered is biofeedback. Patients with motor dysfunction after lower-limb injury or surgery are actively managed by physical therapists and primary care providers in an outpatient clinical setting.

Comparators

The following practice is currently being used to treat motor dysfunction: standard of care. Patients with motor dysfunction after lower-limb injury or surgery are actively managed by physical therapists and primary care providers in an outpatient clinical setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Though not completely standardized, follow-up for motor dysfunction after lower-limb injury or surgery symptoms would typically occur in the months to years after starting treatment.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

A systematic review by Silkman and McKeon (2010) evaluated the effectiveness of EMG biofeedback for improving muscle function during knee rehabilitation after injury.²³ 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 four studies found a statistically significantly greater benefit in the programs that included biofeedback, while the others did not. The positive studies assessed intermediate outcomes (e.g., contraction values of the quadriceps muscles). None of the studies were designed to assess functional outcomes.

Section Summary: Motor Dysfunction After Lower-Limb Injury or Surgery

A systematic review identified four RCTs. Evidence from these trials was limited due to small sample sizes, inconsistent results, and the measurement of intermediate outcomes rather than functional outcomes.

Multiple Sclerosis**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with MS.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with MS?

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

Patients

The relevant population of interest are individuals with MS.

Interventions

The therapy being considered is biofeedback. Patients with MS are actively managed by neurologists, physical therapists, and primary care providers in an outpatient setting.

Comparators

The following practice is currently being used to treat multiple sclerosis: standard of care. Patients with MS are actively managed by neurologists, physical therapists, and primary care providers in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at three weeks is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Randomized Controlled Trials

An RCT by MacKay et al (2015) evaluated the addition of biofeedback to standard care in 40 patients with relapsing-remitting MS patients.²⁴ The standard of care psychosocial intervention consisted of relaxation, mindfulness, social support, and education. All patients attended one-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 three 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. For example, the differences between the intervention group and the control group in breathing rate were 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 received similar amounts of provider contact, so nonspecific intervention effects were not an issue.

Observational Studies

A crossover study by van der Logt et al (2016) evaluated the effect of vibrotactile biofeedback for trunk sway on balance control in patients with multiple sclerosis.²⁵ 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 a 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.

Section Summary: MS

Two RCTs using biofeedback techniques for the treatment of MS were identified. The sample sizes were small, with no statistically 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

Clinical Context and Therapy Purpose

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with orthostatic hypotension due to spinal cord injury.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with orthostatic hypotension due to spinal cord injury?

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

Patients

The relevant population of interest are individuals with orthostatic hypotension due to spinal cord injury.

Interventions

The therapy being considered is biofeedback. Patients with orthostatic hypotension due to spinal cord injury are actively managed by neurologists in an outpatient setting.

Comparators

The following practice is currently being used to treat orthostatic hypotension: standard of care. Patients with orthostatic hypotension due to spinal cord injury are actively managed by neurologists in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Though not completely standardized, follow-up for orthostatic hypotension due to spinal cord injury symptoms would typically occur in the months to years after starting treatment.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

Gillis et al (2008) conducted a systematic review to assess the literature on the non-pharmacologic management of orthostatic hypotension during the early rehabilitation of persons with spinal cord injury.²⁶ 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, and only two studies evaluated biofeedback. These 2 studies, which assessed 3 patients using biofeedback techniques, reported an average of 39% increase in systolic blood pressure. Reviewers 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 the nonpharmacologic management of orthostatic hypotension in patients with spinal cord injury identified two studies using biofeedback. While the studies showed that biofeedback raised systolic blood pressure effectively, only three patients were assessed. Additional research with larger sample sizes is needed.

Pain Management during Labor**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients who need pain management during labor.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients who need pain management during labor?

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

Patients

The relevant population of interest are women needing pain management during labor.

Interventions

The therapy being considered is biofeedback. Women needing pain management during labor are actively managed by anesthesiologists in an inpatient setting.

Comparators

The following practice is currently being used to manage pain during labor: standard of care. Women needing pain management during labor are actively managed by anesthesiologists in an inpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Though not completely standardized, follow-up for pain management during labor symptoms would typically occur in the days to weeks in the postnatal period.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

In a Cochrane review, Barragan Loayza et al (2011) evaluated RCTs on the use of biofeedback for managing pain during labor.²⁷ 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 (e.g., unclear description of blinding and randomization methods). Overall, they found little difference in reported outcomes (e.g., 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 four 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**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with PTSD.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with PTSD?

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

Patients

The relevant population of interest are individuals with PTSD.

Interventions

The therapy being considered is biofeedback. Patients with PTSD are actively managed by psychologists and other mental health professionals in an outpatient setting.

Comparators

The following practice is currently being used to treat PTSD: standard of care. Patients with PTSD are actively managed by psychologists and other mental health professionals in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Though not completely standardized, follow-up for PTSD symptoms would typically occur in the months to years after starting treatment.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

The 2014 Canadian Agency for Drugs and Technology in Health report on biofeedback for mood and anxiety disorders (previously discussed), included a systematic review of the literature on biofeedback for PTSD.³ One systematic review was identified; in it, Wahbeh et al (2014) assessed various complementary and alternative medicine approaches to treating PTSD.²⁸ Four of 33 studies that met the selection criteria of the Wahbeh et al (2014) review addressed biofeedback. Among the biofeedback studies were one RCT, one nonrandomized trial, and two 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 four studies using biofeedback techniques. Results from these studies were inconsistent. Larger controlled trials are needed.

Prevention of Preterm Birth**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for women susceptible to preterm birth.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in women who are susceptible to preterm birth?

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

Patients

The relevant population of interest are women who are susceptible to preterm birth.

Interventions

The therapy being considered is biofeedback. Women susceptible to preterm birth are actively managed by obstetricians and primary care providers in an outpatient setting.

Comparators

The following practice is currently being used to manage preterm birth: standard of care. Women susceptible to preterm birth are actively managed by obstetricians and primary care providers in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Treatment of two weeks is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Randomized Controlled Trials

Siepmann et al (2014) published data on 48 female candidates for preterm labor between the 24th and the 32nd gestational week.²⁹ Twenty-four women received 6 biofeedback sessions over 2 weeks, and the other 24 women received usual care. 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 was identified; it used biofeedback techniques to prevent preterm birth. There was no statistically significant difference between the biofeedback group and the control group in regard to the number of preterm deliveries or birthweight.

Raynaud Disease**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with Raynaud disease.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with Raynaud disease?

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

Patients

The relevant population of interest are individuals with Raynaud disease.

Interventions

The therapy being considered is biofeedback. Patients with Raynaud disease are actively managed by rheumatologists and primary care providers in an outpatient setting.

Comparators

The following practice is currently being used to treat Raynaud disease: standard of care. Patients with Raynaud disease are actively managed by rheumatologists and primary care providers in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at one year is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

A systematic review by Malenfant et al (2009) assessed the use of complementary and alternative medicine to treat Raynaud disease.³⁰ Reviewers identified five 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 two arms; in the preceding analysis, only the arms comparing active with sham biofeedback were included.

Randomized Controlled Trials

The trial given the highest quality rating in the Malenfant systematic review and with the largest sample size is the Raynaud's Treatment Study, published in 2000.³¹ This randomized trial compared sustained-release nifedipine with thermal biofeedback in 313 patients with primary Raynaud disease. In addition to these two treatment groups, there were two 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 no significant

difference between attack rates in the nifedipine and thermal biofeedback groups for the primary outcome ($p=0.08$).

Section Summary: Reynaud Disease

A systematic review identified five 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**Clinical Context and Therapy Purpose**

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with sleep bruxism.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with sleep bruxism?

The following PICO's were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with sleep bruxism.

Interventions

The therapy being considered is biofeedback. Patients with sleep bruxism are actively managed by dentists, physical therapists, psychologists, and primary care providers in an outpatient setting.

Comparators

The following practice is currently being used to treat sleep bruxism: standard of care. Patients with sleep bruxism are actively managed by dentists, physical therapists, psychologists, and primary care providers in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Treatment and follow-up of six weeks are of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Systematic Reviews

Wang et al (2014) published a systematic review of RCTs and non-RCTs evaluating biofeedback treatment for sleep bruxism.³² Seventeen articles were 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 durations ranged from one night to six weeks. In four studies, the treatment duration was two weeks. Three studies 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.

Jokubauskas et al (2018) updated the systematic review by Wang et al (2014) (above) on the management of sleep bruxism with biofeedback.³³ Five databases were searched for literature published after the original 2012 search. Six relevant publications were included (total $n=86$ adults), and of these studies, 4 were RCTs and 2 were uncontrolled before-after studies. For the

quantitative synthesis, two additional studies were included from the original Wang et al (2014) review. Contingent electrical stimulation, audio feedback, and a maxillary biofeedback splint were among the biofeedback techniques investigated, and all studies measured sleep bruxism with EMG with the exception of one, which used a mini wireless biofeedback device that analyzed bite force. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Secondary outcomes of sleep quality and pain-related outcomes were also investigated in the studies, and one study reported on patient-perceived symptom change. Overall, the quality of these studies was assessed as low to moderate due to imprecision and inconsistency between studies, and the risk of bias was graded as high to moderate. Despite the limitations of the studies, the use of biofeedback to treat sleep bruxism has shown some effectiveness and is relatively safe and noninvasive.

Randomized Controlled Trials

Sato et al (2015) published a trial on the use of EMG biofeedback training for daytime clenching and its effect on sleep bruxism.³⁴ Patients were monitored for five hours of daytime and nighttime 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 two and three in the biofeedback group during the daytime, and the decreases in events carried over into the nighttime. There were no decreases in EMG events in the control group.

One of the larger RCTs (n=57) was reported by Ommerborn et al (2007), who 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.³⁵ 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 trial, and thus conclusions cannot be drawn about its effectiveness compared with occlusal splinting.

Section Summary: Sleep Bruxism

One systematic review identified 17 studies using biofeedback techniques to treat sleep bruxism, and another more recent systematic review update was performed identifying 6 new studies but no new significant data. Pooled analyses of two 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 permit additional pooled analyses. An RCT published after the review, which tested EMG 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

Clinical Context and Therapy Purpose

The purpose of biofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with tinnitus.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with tinnitus?

The following PICO's were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with tinnitus.

Interventions

The therapy being considered is biofeedback. Patients with tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient setting.

Comparators

The following practice is currently being used to treat tinnitus: standard of care. Patients with tinnitus are actively managed by otolaryngologists and primary care providers in an outpatient setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Treatment or follow-up of three months is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the same principles outlined in indication 1.

Randomized Controlled Trials

An RCT by Weise et al (2008) investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany.³⁶ 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 for over 3 months. 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 its 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 range of 0 to 84. The preassessment mean in the Tinnitus Questionnaire total score was 54.⁷ and the post-assessment mean was 32.5.

Section Summary: Tinnitus

A single RCT was identified and it 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.

Summary of Evidence

For individuals with anxiety disorders who receive biofeedback, the evidence includes two systematic reviews and an RCT published after the review. The relevant outcomes are symptoms, functional outcomes, and QOL. The systematic reviews and observational trial on HRVB and the RCT on DBR 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 technology on net health outcomes.

For individuals with asthma who receive biofeedback, the evidence includes five RCTs. The relevant outcomes are symptoms, functional outcomes, and QOL. Each RCT 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 for which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. However, one RCT led to the conclusion that biofeedback has promise as a protective approach to aiding lung function and reducing stress-induced asthma exacerbation. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals with Bell palsy who receive biofeedback, the evidence includes four RCTs. The relevant outcomes are symptoms, functional outcomes, and QOL. The RCTs evaluated the efficacy of adding a mirror and/or electromyography biofeedback to facial exercises. The

sample sizes were small, and there was heterogeneity across techniques used and length of treatments. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals with depression who receive biofeedback, the evidence includes a systematic review. The relevant outcomes are symptoms, functional outcomes, and QOL. The review only identified two dissertations assessing the use of biofeedback for depression. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals with hypertension who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. The relevant outcomes are symptoms, functional outcomes, and QOL. 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 HRV. 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 technology on net health outcomes.

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews, RCTs published after the systematic reviews, and a case series. The relevant outcomes are symptoms, functional outcomes, and QOL. One 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 primarily assessed motor activity in research settings, rather than clinical outcomes such as rates of falls or the 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 technology on net health outcomes.

For individuals with motor dysfunction after lower-limb injury or surgery who receive biofeedback, the evidence includes a systematic review. The relevant outcomes are symptoms, functional outcomes, and QOL. The systematic review identified four 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 technology on net health outcomes.

For individuals with MS who receive biofeedback, the evidence includes two RCTs. The relevant outcomes are symptoms, functional outcomes, and QOL. 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 technology on net health outcomes.

For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a case series and a case report. The relevant outcomes are symptoms, functional outcomes, and QOL. The case series and a case report collectively provided information on three 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 technology on net health outcomes.

For individuals who need pain management during labor who receive biofeedback, the evidence includes four RCTs. The relevant outcomes are symptoms, functional outcomes, and QOL. A Cochrane review graded the four 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 technology on net health outcomes.

For individuals with PTSD who receive biofeedback, the evidence includes an RCT, a non-randomized study, and two case series. The relevant outcomes are symptoms, functional outcomes, and QOL. The studies had small sample sizes and inconsistent results. A systematic review of the four studies rated the evidence a grade C for conflicting scientific evidence. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, and QOL. In the RCT, women 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 birth weight. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals with Raynaud disease who receive biofeedback, the evidence includes a systematic review. The relevant outcomes are symptoms, functional outcomes, and QOL. The systematic review identified five RCTs using biofeedback techniques. Pooled analysis was performed on four of these trials. The reduction in the frequency of attacks was significantly lower in the sham control group. The evidence is insufficient to determine the effects of technology on net health outcomes.

For individuals with sleep bruxism who receive biofeedback, the evidence includes two systematic reviews and an RCT published after the review. The relevant outcomes are symptoms, functional outcomes, and QOL. One systematic review identified seven randomized and non-randomized studies using biofeedback techniques, and the most recent systematic review identified six additional studies. 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 technology on net health outcomes.

For individuals with tinnitus who receive biofeedback, the evidence includes a single RCT. The relevant outcomes are symptoms, functional outcomes, and QOL. Treatment consisted of a biofeedback-based behavioral intervention over a three-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 technology on net health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American Psychiatric Association

The American Psychiatric Association (2010) guidelines on the treatment of patients with major depressive disorder did not list biofeedback as a potential treatment.³⁷

The Association's (2004) guidelines on the treatment of patients with acute stress disorder and posttraumatic stress disorder mentioned the use of biofeedback to augment relaxation techniques.³⁸ 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

The American Academy of Sleep Medicine (2017) released guidelines on the evaluation and management of chronic insomnia in adults.³⁹ The guidelines listed biofeedback as one of several behavioral or psychological therapies to reduce chronic somatic arousal.

Scottish Intercollegiate Guidelines Network

The Scottish Intercollegiate Guidelines Network (2010) 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."⁴⁰

American Academy of Neurology

As of September 2019, the American Academy of Neurology has made no recommendations regarding the use of biofeedback for multiple sclerosis, Bell palsy, or orthostatic hypotension due to spinal cord injury.

The American College of Cardiology et al (2017) guidelines on hypertension in adults states that "behavioral therapies, including....biofeedback, lack strong evidence for their long-term BP-lowering effect."⁴¹

As of September 2019, the American College of Obstetricians and Gynecologists has made no recommendations on the use of biofeedback for pain management during labor or to prevent preterm birth.

U.S. Preventive Services Task Force Recommendations

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

Medicare National Coverage

Medicare covers biofeedback:

"....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 the treatment of ordinary muscle tension states or for psychosomatic conditions."⁴²

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02667392	Biofeedback to Increase Propulsion During Walking after Stroke	30	Sep 2019
NCT02998502	Efficacy of a Biofeedback Breathing System for Anxiety and Panic Disorders	60	Sep 2019
NCT03039231	Investigation of the Freespira Breathing System in the Treatment of Post-traumatic Stress Disorder	55	Oct 2019
Unpublished			
NCT03030326	Biofeedback for Asthma Comorbid with Anxiety or Depression	20	Dec 2020 (withdrawn due to lack of funding and staff)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02237885	Pain Management Using Mobile Technology in Veterans with Post-traumatic Stress Disorder and Traumatic Brain Injury	41	Nov 2017 (completed; last updated Dec 2017)
NCT02119936	Feasibility of Heart Rate Variability Feedback as a Stress Reduction Tool for Hospitalized Pregnant Women	30	Dec 2016 (terminated due to lack of funding)

NCT: national clinical trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

Type	Code	Description
CPT®	90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes

Type	Code	Description
	90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
	90901	Biofeedback training by any modality
HCPCS	E0746	Electromyography (EMG), biofeedback device

Policy History

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

Effective Date	Action
10/01/2010	New policy Combined with the previously existing BSC Medical Policy: <ul style="list-style-type: none"> Neurofeedback
04/05/2013	Policy revision with position change
09/30/2014	Policy title change from Biofeedback Policy revision with position change
01/01/2017	Policy revision without position change
10/01/2017	Policy revision without position change
10/01/2018	Policy revision without position change
02/01/2019	Policy revision without position change
02/01/2020	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

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

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

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

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an

authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

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

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.