2.01.53	Biofeedback for Miscellaneous Indications		
Original Policy Date:	October 1, 2020	**Effective Date:**	February 1, 2024
Section:	2.0 Medicine	**Page:**	Page 1 of 35

Policy Statement

I. Biofeedback is considered **investigational** as a treatment of the following miscellaneous conditions:
   A. Anxiety disorders
   B. Asthma
   C. Bell palsy
   D. Depression
   E. Hypertension
   F. Insomnia
   G. Movement disorders, such as motor function after stroke, injury, or lower-limb surgery
   H. Multiple sclerosis
   I. Orthostatic hypotension in individuals with spinal cord injury
   J. Pain management during labor
   K. Posttraumatic stress disorder
   L. Prevention of preterm birth
   M. Raynaud disease
   N. Sleep bruxism
   O. Tinnitus

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

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

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

Since 1976, a large number of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA Product Code: HCC.

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, 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. Evidence pertaining to the use of biofeedback for chronic insomnia is addressed in Blue Shield of California Medical Policy: Neurofeedback. Evidence pertaining to the use of biofeedback for chronic pain is addressed in Blue Shield of California Medical Policy: Biofeedback as a Treatment of Chronic Pain. Evidence pertaining to the use of biofeedback for headache is addressed in Blue Shield of California Medical Policy: Biofeedback as a Treatment of Headache. Evidence pertaining to the use of biofeedback for urinary incontinence is addressed in Blue Shield of California Medical Policy: Biofeedback as a Treatment of Urinary Incontinence in Adults. Evidence pertaining to the use of biofeedback for fecal incontinence or constipation is addressed in Blue Shield of California Medical Policy: Biofeedback as a Treatment of Fecal Incontinence or Constipation.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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, 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 individuals with anxiety disorders.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with anxiety disorders.

Interventions

The therapy being considered is biofeedback.

Comparators
The following practices are currently being used to treat anxiety disorders: standard of care.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at 8 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.
- Studies with larger sample sizes were preferred.

Review of Evidence
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.[1,] Heart rate variability is a measure of cardiac vagal tone. Low HRV is associated with certain psychological states such as anxiety. The literature search identified 24 studies (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. Only 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 (2017) published an update to their rapid response report on biofeedback for treating mood and anxiety disorders.[2,] 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 with routine respiration activities in the treatment of 46 patients with anxiety.[3,] Diaphragmatic breathing relaxation 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 4 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 diaphragmatic breathing relaxation 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 diaphragmatic breathing relaxation group experienced statistically significant decreases in Beck Anxiety Inventory scores compared with baseline, while the control group did not. The diaphragmatic

breathing relaxation group also experienced significant improvements in all 4 physiological measurements, while the control group did not.

Section Summary: Anxiety Disorders

For individuals with anxiety disorders who receive biofeedback, the evidence includes 2 systematic reviews and an RCT published after the review. A systematic review on HRVB and an RCT on diaphragmatic breathing relaxation reported the positive effects of these treatments on anxiety. However, the trials in the systematic review 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.

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 individuals with asthma.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with asthma.

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat asthma: standard of care.

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 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.
- Studies with larger sample sizes were preferred.

Review of Evidence

Systematic Reviews

Yorke et al (2015) published a systematic review evaluating nonpharmacologic interventions for the treatment of adults with asthma.[4,] 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)[5,]; HRV using a physiograph (pooled n=94 patients)[6,]; and respiratory sinus arrhythmia by electrocardiographic feedback and muscle tension by electromyography (EMG; pooled n=17

patients).[7,] Common outcomes in the 3 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 1 trial. Reviewers concluded that larger sample sizes were needed to demonstrate effects and 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.[8,] 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 4 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 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 ($p=.002$) and forced vital capacity percent ($p<.001$) 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 induce 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.[9,] In the 2-center trial, 68 paid steroid-naive 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

For individuals with asthma who receive biofeedback, the evidence includes a systematic review of 3 RCTs and 2 RCTs published after the review. Each RCT used a different biofeedback technique, which provided individuals 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, the results of 1 RCT suggested that biofeedback has promise as a protective approach to aiding lung function and reducing stress-induced asthma exacerbation.

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 individuals with Bell palsy.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest are individuals with Bell palsy.

Interventions
The therapy being considered is biofeedback.

Comparators
The following practices are currently being used to treat Bell palsy: standard of care.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up over 1 to 12 months 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.
- Studies with larger sample sizes were preferred.

Review of Evidence
Systematic Reviews
Cardoso et al (2008) published a systematic review on the effects of facial exercises on symptoms of Bell palsy.[10,] Studies including patients with unilateral idiopathic facial palsy treated with facial exercises associated with mirror and/or EMG biofeedback were selected. Four studies (N=132 patients) met the eligibility criteria. The studies described mime therapy versus control (n=50 patients), mirror biofeedback exercise versus control (n=27 patients), "small" mirror movements versus conventional neuromuscular retraining (n=10 patients), and EMG biofeedback plus mirror training versus 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
For individuals with Bell palsy who receive biofeedback, the evidence includes a systematic review of 4 RCTs. The RCTs evaluated the efficacy of adding a mirror and/or EMG biofeedback to facial exercises. The sample sizes were small, and there was heterogeneity across 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 individuals with depression.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest are individuals with depression.

Interventions
The therapy being considered is biofeedback.

Comparators
The following practices are currently being used to treat depression: standard of care.

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

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.
- Studies with larger sample sizes were preferred.

Review of Evidence
Systematic Reviews
The Canadian Agency for Drugs and Technology in Health (2014) report on biofeedback for mood and anxiety disorders [11] 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. An update was published in 2017 (previously discussed in the Anxiety section).[2] An additional dissertation using Within HRVB was included, but no other relevant studies for the treatment of depression were identified.

Randomized Controlled Trials
Since the publication of this systematic review, 2 small RCTs have been published; the characteristics, results, and limitations of these trials are summarized in Tables 1 through 4. Maynart et al (2021) compared respiratory and heart rate biofeedback plus usual care to usual care alone in 36 patients with moderate to severe depression or dysthymia.[12] After 6 weeks (6 sessions of biofeedback training), the biofeedback plus usual care group had less severe depression as measured by the Beck Depression Inventory (BDI) than the usual care alone group. An additional preliminary open-label RCT by Park and Jung (2020) compared respiratory sinus arrhythmia biofeedback plus usual care to usual care alone in 30 Korean patients with major depressive disorder.[13] After 4 weeks (6 sessions of biofeedback), the biofeedback plus usual care group had greater improvements in Hamilton Depression Rating Scale (HAM-D) scores compared to the group receiving usual care alone.

Improvements in other clinical measures, including the BDI, were not significantly different between groups.

Table 1. Summary of Key RCT Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active Treatment	Comparator
Maynart et al (2021)[12]	Brazil	3	NR	Adults aged 18 years or older with major depressive disorder or dysthymia treated with	Respiratory rate and blood volume	Usual care alone (n=18)

Study	Countries	Sites	Dates	Participants	Interventions	
				antidepressants and BDI score of 20 to 63	pulse/heart rate biofeedback plus usual care (n=18)	
Park and Jung (2020)[13,]	South Korea	1	2015-2018	Adults aged 20 to 60 years with major depressive disorder and HAM-D score of 16 or greater	Respiratory sinus arrhythmia biofeedback (6 sessions) plus usual care (n=16)	Usual care alone (n=14)

BDI: Beck Depression Inventory; HAM-D: Hamilton Depression Rating Scale; NR: not reported; RCT: randomized controlled trial.

Table 2. Summary of Key RCT Results

Study	HAM-D	BDI
Maynart et al (2021)[12,]		*% in each BDI severity category at 6 weeks*
Biofeedback plus usual care	NR	Minimum: 16.7% Light: 19.4% Moderate: 13.9% Severe: 0%
Usual care alone	NR	Minimum: 2.8% Light: 13.9% Moderate: 30.6% Severe: 2.8%
p value	NR	.046
Park and Jung (2020)[13,]	*Mean HAM-D score at week 4*	*Mean BDI score at week 4*
Biofeedback plus usual care	8.92	24.33
Usual care alone	14.55	25.45
p value	.0229	.7657

BDI: Beck Depression Inventory; HAM-D: Hamilton Depression Rating Scale; NR: not reported; RCT: randomized controlled trial.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Maynart et al (2021)[12,]			3. No sham biofeedback intervention was administered to the control group		1. Primary outcomes were assessed at the end of 6 weeks; no information available on long-term impact of biofeedback
Park and Jung (2020)[13,]			3. No sham biofeedback intervention was administered to the control group		1. Primary outcomes were assessed at the end of 4 weeks; no information available on long-term impact of biofeedback

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Maynart et al (2021)[12,]		1,2. Open label design			1. Power calculations not detailed	
Park and Jung (2020)[13,]		1,2. Open label design				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Depression

For individuals with depression who receive biofeedback, the evidence includes a systematic review and 2 small RCTs published after the systematic review. The review and its update only identified 3 dissertations assessing the use of biofeedback for depression. One RCT found that respiratory and heart rate biofeedback plus usual care reduced BDI scores compared to usual care alone, while the other found that respiratory sinus arrhythmia biofeedback plus usual care was associated with greater improvements in HAM-D scores compared to usual care alone; however, these trials were limited by open-label designs, short follow-up periods, and small sample sizes.

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 individuals with hypertension.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with hypertension.

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat hypertension: standard of care.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at 6 months 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.
- Studies with larger sample sizes were preferred.

Review of Evidence
Systematic Reviews
A systematic review of studies on biofeedback for hypertension was published by Greenhalgh et al (2009).[14,] 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 (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 1 modality. Twenty studies evaluated biofeedback alone, 15 evaluated biofeedback combined with another intervention, and 1 had multiple arms and evaluated both types of interventions; only 4 trials included a sham biofeedback comparison group. 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 in patients with prehypertension or stage I hypertension.[15,] 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 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 could effectively lower blood pressure, regardless of the type of feedback signal.

Mengden et al (2023) published a randomized cohort study evaluating the effect of device-guided slow breathing with biofeedback of pulse wave velocity in patients with hypertension.[16,] Patients (N=44) were trained to perform unattended device-guided slow breathing exercises for 10 minutes daily over 5 days. At the time of initial screening, office-measured blood pressure was median 137/83 mmHg. After the first 10 minute daily exercise, a significant increase (p<.05) in pulse wave velocity of 5 ms on average was observed. Additionally, between the initial baseline collection of blood pressure and self-assessment before beginning the breathing assessment, there was a significant decrease of 6 mmHg (p<.001) in systolic blood pressure, possibly accounting for white coat effect. Another significant 5 mmHg (p<.001) decrease in systolic blood pressure occurred post-assessment. Similar changes were seen daily after each biofeedback session. However, there were no significant changes between day 1 values and day 5 values.

Section Summary: Hypertension

For individuals with hypertension who receive biofeedback, the evidence includes a systematic review and 2 RCTs published after the review. 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 shortage of studies isolating the effect of biofeedback, the generally poor quality of trials, and heterogeneity across interventions used. The Mengden 2023 RCT demonstrated an acute change in blood pressure after a 10-min biofeedback session, but no longer term effects were demonstrated over the course of a week.

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 individuals with motor dysfunction after stroke.

The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat motor dysfunction after stroke: standard of care.

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 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.

- Studies with larger sample sizes were preferred.

Review of Evidence

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.[17,18,] Only high-quality RCTs or quasi-RCTs with Physiotherapy Evidence Database scores greater than 4 were included. Training activities were walking (9 trials), standing (8 trials), and standing up (1 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 7 trials, auditory in 7 trials, and a combination of visual and auditory in 4 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 4 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.[19,] 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 1 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 3 studies reported long-term outcomes, and none of them reported a significant effect of biofeedback.

Table 5 summarizes the characteristics of selected systematic reviews.

Table 5. Characteristics of the Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Stanton et al (2017)[17,]	To 2015	18	Lower-limb motor function loss poststroke	429 (12 to 50)	RCTs	NR
Zijlstra et al (2010)[19,]	1993-2012	21	Patients >60 years receiving biofeedback to improve motor function	NR (5 to 30)	17 RCTs, 4 other	NR

NR: not reported; RCT: randomized controlled trial.

Randomized Controlled Trials

Several RCTs have been published since the systematic reviews discussed above; these studies are described here. The RCTs that reported outcomes in at least 40 patients are highlighted in Tables 6 through 9.

Ambrosini et al (2020) published an RCT on the effect of visual biofeedback on gait and walking ability in patients who have had a first-time stroke.[20,] Patients were randomized to receive 20 minutes of visual biofeedback training and 70 minutes of usual rehabilitation care (n=34) or 90 minutes of usual rehabilitation care (n=34). Characteristics, results, and limitations of this trial are summarized in the tables below. Groups experienced similar improvements in gait speed, 6-minute walking test, Functional Independence Measure scores, and Berg Balance Test scores, with no significant differences between groups observed. Outcomes were reported at the end of 6 weeks of treatment; although follow-up was attempted at 6 months, over half of the patients were

unavailable for follow-up assessments, so longer-term effects of biofeedback training could not be assessed.

Ghanbari Ghoshchi et al (2020) published an RCT on the effects of technological rehabilitation (using audio or visual biofeedback) on activities of daily living and return to work among 48 patients who have had a stroke.[21,] All patients attended 3 rehabilitation sessions per day on 3 days per week for 1 month; each session was 40 minutes in length. Patients randomized to the technological rehabilitation group had 400 minutes of audio or visual biofeedback training included in their rehabilitation sessions. Ability to perform activities of daily living was measured using the modified Barthel Index. Trial characteristics, results, and limitations are summarized in the tables below. No significant between-group differences were observed 6 months after therapy was completed. Return to work may have been influenced by other factors, including patient age, economic status, and previous occupation.

Kim (2017) published an RCT on the effect of EMG on upper-extremity function in patients who have had a stroke.[22,] 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.[23,] 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.[24,] 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.

Table 6. Summary of Key RCT Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active Treatment	Comparator
Ambrosini et al (2020)[20,]	Italy	1	2015-2018	Adults aged 18 to 90 years in an inpatient rehabilitation facility with first stroke <6 months prior to recruitment and hemiparesis; had to have lower limb range of motion that allowed pedaling and reduced spasticity of leg muscles (Modified Ashworth scale <2)	20 minutes of visual biofeedback training (voluntary cycling augmented by functional electrical stimulation or platform-based balance training) plus 70 minutes of usual care per session; 30 sessions (n=34)	90 minutes of usual care per session; 30 sessions (n=34)

Study	Countries	Sites	Dates	Participants	Interventions	
Ghanbari Ghoshchi et al (2020)[21,]	Italy	3	NR	Adults aged 18 to 66 years in neurorehabilitation hospitals with stroke >6 months prior to the study who were working at the time of their stroke	Technological rehabilitation; patients received 400 minutes total of audio or visual biofeedback via SonicHand or Riablo devices as part of their rehab sessions, in addition to conventional exercises (n=23)	Conventional rehabilitation; patients performed conventional rehabilitation exercises only for the same total amount of time (n=25)

NR: not reported; RCT: randomized controlled trial.

Table 7. Summary of Key RCT Results

Study	Gait speed	6-minute walking test	Functional Independence Measure	Berg Balance Test	Modified Barthel Index	Return to work	Fall events
Ambrosini et al (2020)[20,]	*Change from baseline to posttreatment*	*Change from baseline to posttreatment*	*Change from baseline to posttreatment in the motor subscale*	*Change from baseline to posttreatment*			
Biofeedback	27.7 cm/s	110.2 m	35	21	NR	NR	NR
Usual care	21.3 cm/s	76.1 m	31	18	NR	NR	NR
p value	.305	.120	.451	.211	NR	NR	NR
Ghanbari Ghoshchi et al (2020)[21,]						*At 6-month follow-up*	*At 6-month follow-up*
Technological rehabilitation with biofeedback	NR	NR	NR	NR	Postrehab: 88 6-month follow-up: 100	11 (47.8%)	5 (21.7%)
Conventional rehabilitation	NR	NR	NR	NR	Postrehab: 80 6-month follow-up: 95	9 (36.0%)	4 (16.0%)
p value	NR	NR	NR	NR	Postrehab:.391 6-month follow-up:.450	.406	.611

NR: not reported; RCT: randomized controlled trial.

Table 8. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Ambrosini et al (2020)[20,]					1. Primary outcomes were assessed at the end of 6 weeks of treatment; 6-month follow-up was attempted, but 53% of patients were not available for assessment
Ghanbari Ghoshchi et al (2020)[21,]					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ambrosini et al (2020)[20],		1. Single-blind design (patients not blinded)		1. High drop-out rate (24% at posttreatment time point, 53% at 6-month follow-up)		
Ghanbari Ghoshchi et al (2020)[21],		1. Single-blind design (patients not blinded)			1. Power calculations not reported	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Motor Dysfunction After Stroke

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews and RCTs published after the systematic reviews. One systematic review identified 18 high-quality trials using the following biofeedback techniques: weight distribution on a platform sensor, muscle activity from EMG, 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 largest available studies published since the systematic reviews found no differences between biofeedback-assisted rehabilitation and conventional rehabilitation in terms of their impact on gait speed, balance, activities of daily living, fall rate, and return to work.

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 individuals with motor dysfunction after lower-limb injury or surgery.

The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat motor dysfunction after lower-limb injury or surgery: standard of care.

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 would typically occur in the months to years after starting treatment.

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.
- Studies with larger sample sizes were preferred.

Review of Evidence

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.[25,] 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 (e.g., contraction values of the quadriceps muscles). None of the studies were designed to assess functional outcomes.

A systematic review and meta-analysis by Xie et al (2021) included 6 RCTs (N=222) comparing postsurgical knee rehabilitation programs with and without EMG biofeedback.[26,] Sample sizes of individual trials ranged from 16 to 66 patients. In a meta-analysis of data from 5 RCTs (n=146), range of motion was improved with biofeedback (standardized mean difference, -0.48; 95% CI, -0.82 to -0.14; p=.006; I^2=37%). However, 4 of the 5 individual trials in the range of motion analysis found no significant benefit with EMG biofeedback compared to conventional rehabilitation methods; only the smallest trial (N=16), measuring passive range of motion 6 weeks after anterior cruciate ligament reconstruction, found a significant improvement with EMG biofeedback. The studies were

heterogenous in terms of the intervention intensity, the comparators used, and the type of knee surgery, as well as the specific range of motion endpoint used (passive vs. active range of motion). The range of motion findings of the meta-analysis may have been driven by the strong positive findings in a single trial, and may not be generalizable to other settings. Biofeedback was not associated with greater improvements in pain or physical function. Trials were generally limited by small sample sizes and short follow-up periods.

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

For individuals with motor dysfunction after lower-limb injury or surgery who receive biofeedback, the evidence includes 2 systematic reviews. One systematic review identified 4 RCTs evaluating the use of EMG biofeedback in patients undergoing postinjury knee rehabilitation. 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 other systematic review identified 6 RCTs evaluating the use of EMG biofeedback in patients undergoing postsurgical knee rehabilitation. Biofeedback was associated with better range of motion outcomes in a meta-analysis of data from 5 RCTs, but was not associated with a significant benefit in terms of pain or physical functioning. Larger and longer-term trials are still needed that demonstrate benefits on quality of life and 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 individuals with multiple sclerosis (MS).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with MS.

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat MS: standard of care.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at 3 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.
- Studies with larger sample sizes were preferred.

Review of Evidence

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.[27,] 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. For example, the differences between the intervention group and the control group in breathing rate were 3.06 breaths per minute (95% CI, -0.17 to 6.28 breaths per minute; p=.06) and the difference in muscle tension was -13.91 µV (95% CI, -30.06 to 2.25 µV; p=.09). Both groups received similar amounts of provider contact, so nonspecific intervention effects were not an issue.

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 MS.[28,] 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: Multiple Sclerosis

For individuals with MS who receive biofeedback, the evidence includes 2 RCTs. One trial used vibrotactile biofeedback and the other provided patients with breathing rate and muscle tension biofeedback. The sample sizes were small, with no statistically significant differences between the biofeedback groups and control groups.

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 individuals with orthostatic hypotension due to spinal cord injury.

The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat orthostatic hypotension due to spinal cord injury: standard of care.

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 would typically occur in the months to years after starting treatment.

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.
- Studies with larger sample sizes were preferred.

Review of Evidence

Systematic Reviews

Gillis et al (2008) conducted a systematic review to assess the literature on the nonpharmacologic management of orthostatic hypotension during the early rehabilitation of persons with spinal cord injury.[29,] 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 (N=138 patients) were included in the review. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified, and only 2 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 orthostatic hypotension has not been proven."

Section Summary: Orthostatic Hypotension in Patients With Spinal Cord Injury

For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a systematic review, which included a case series and a case report. The case series and case report 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%.

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 individuals who need pain management during labor.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals who need pain management during labor.

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to manage pain during labor: standard of care.

Outcomes

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

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.
- Studies with larger sample sizes were preferred.

Review of Evidence

Systematic Reviews

In a Cochrane review, Barragan Loayza et al (2011) evaluated RCTs on the use of biofeedback for managing pain during labor.[30,] Reviewers identified 4 RCTs published between 1982 and 2000 (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

For individuals who need pain management during labor who receive biofeedback, the evidence includes a systematic review of 4 RCTs. A Cochrane review graded the 4 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.

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 individuals with posttraumatic stress disorder (PTSD).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with PTSD.

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat PTSD: standard of care.

Outcomes

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

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.
- Studies with larger sample sizes were preferred.

Review of Evidence
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.[11,] One systematic review was identified; in it, Wahbeh et al (2014) assessed various complementary and alternative medicine approaches to treating PTSD.[31,] Four of 33 studies that met the selection criteria of the Wahbeh et al (2014) 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. An update of the Canadian Agency for Drugs and Technology in Health report was published in 2017 (previously mentioned).[2,] Investigators identified 2 RCTs using biofeedback in patients with PTSD: 1 by Wahbeh et al (2016) compared 4 treatment modalities, including mindfulness meditation, slow breathing using a biofeedback device, mindful awareness of breadth with the intent to do slow breathing, and sitting quietly in combat veterans with PTSD (N=102); the other RCT by Polak et al (2015) compared biofeedback plus trauma-focused cognitive behavioral therapy (CBT) to CBT alone in patients with PTSD (N=8). The smaller study by Polak et al demonstrated that PTSD symptoms decreased over time for both biofeedback plus CBT and CBT alone, but PTSD symptoms decreased faster with biofeedback plus CBT compared to CBT alone (p=.051). The larger RCT by Wahbeh et al showed that there were no between group differences for biofeedback and various other mindfulness related treatment modalities in individuals with PTSD. These results were limited by the small sample size in Polak et al, lack of adverse event reporting, and the small number of studies which did not allow for pooling of results.

Section Summary: Posttraumatic Stress Disorder
For individuals with PTSD who receive biofeedback, the evidence includes a systematic review and its update. The 2014 systematic review included an RCT, a nonrandomized study, and 2 case series. The studies had small sample sizes and inconsistent results. The reviewers rated the evidence a grade C for conflicting scientific evidence. The 2017 systematic review update included 2 new RCTs, 1 of which demonstrated a faster decrease of PTSD symptoms with biofeedback and CBT compared to CBT alone. However, the small sample size was a limitation. The other RCT found no differences between biofeedback and other treatment modalities.

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 individuals who are susceptible to preterm birth.

The following PICO was used to select literature to inform this review.

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

Interventions
The therapy being considered is biofeedback.

Comparators
The following practices are currently being used to manage patients who are susceptible to preterm birth: standard of care.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at 2 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.
- Studies with larger sample sizes were preferred.

Review of Evidence
Randomized Controlled Trials
Siepmann et al (2014) published data on 48 female candidates for preterm labor between the 24th and the 32nd gestational week.[32,] 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>.05). Other gestational outcomes data, such as the gestational duration and birth weight, also did not differ significantly between groups.

Section Summary: Prevention of Preterm Birth
For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes an RCT. In the RCT, women in the treatment group received HRVB. 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.

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 individuals with Raynaud disease.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest are individuals with Raynaud disease.

Interventions
The therapy being considered is biofeedback.

Comparators
The following practices are currently being used to treat Raynaud disease: standard of care.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at 1 year 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.
- Studies with larger sample sizes were preferred.

Review of Evidence

Systematic Reviews

A systematic review by Malenfant et al (2009) assessed the use of complementary and alternative medicine to treat Raynaud disease.[33,] 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<.000). Several trials had more than 2 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.[34,] This randomized trial compared sustained-release nifedipine with 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. Electromyography 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<.002), but thermal feedback did not differ significantly from EMG biofeedback (p=.37). There was no significant difference between attack rates in the nifedipine and thermal biofeedback groups for the primary outcome (p=.08).

Section Summary: Raynaud Disease

For individuals with Raynaud disease who receive biofeedback, the evidence includes a systematic review. The systematic review identified 5 RCTs using biofeedback techniques. Pooled analysis was performed on 4 of these trials. The reduction in the frequency of attacks was significantly lower 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 individuals with sleep bruxism.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with sleep bruxism.

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat sleep bruxism: standard of care.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at 6 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.
- Studies with larger sample sizes were preferred.

Review of Evidence
Systematic Reviews
Wang et al (2014) published a systematic review of RCTs and non-RCTs evaluating biofeedback treatment for sleep bruxism.[35,] Seventeen articles were reviewed, and 7 studies (N=240 participants) met the inclusion criteria. Studies were generally small; only 2 included more than 50 participants. Four studies used audio biofeedback, 2 used contingent electric stimulation, and 1 used visual biofeedback. Treatment durations ranged from 1 night to 6 weeks. In 4 studies, the treatment duration was 2 weeks. Three studies had moderate risk of bias, and the other 4 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.[36,] Five databases were searched for literature published after the original 2012 search. Six relevant publications were included (N=86 adults), and of these studies, 4 were RCTs and 2 were uncontrolled before-after studies. For the quantitative synthesis, 3 studies were used, 2 of which 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 1, 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 1 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
One RCT by Bergmann et al (2020) has been published since the systematic reviews discussed above.[37,] This trial (N=41) examined the use of a full-occlusion biofeedback splint for sleep bruxism and pain associated with temporomandibular disorder. The biofeedback splint was compared to an adjusted occlusal splint. The key characteristics and results of the trial are summarized in Tables 10 and 11. Limitations in study relevance, conduct, and design are summarized in Tables 12 and 13. Although a statistically significant difference in total duration of bruxism events per hour was observed at 1 month, this difference was no longer significant at 3 months, and no significant

difference was seen in the number of bursts per hour. Patients in the biofeedback splint group had a greater decrease in general pain perception at 3 months.

Table 10. Summary of Key RCT Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active Treatment	Comparator
Bergmann et al (2020)[37,]	Germany	1	2016-2018	Adults with pain due to TMD and sleep bruxism	Full-occlusion biofeedback splint (n=20)	Adjusted occlusal splint (n=21)

RCT: randomized controlled trials; TMD: temporomandibular disorder.

Table 11. Summary of Key RCT Results

Study	Total duration of bruxism events per hour	Number of bruxism bursts per hour	Pain symptoms
Bergmann et al (2020)[37,]	*Mean change from baseline in seconds of bruxism per hour*	*Mean change from baseline in number of bursts per hour*	*Percent change in general pain perception from baseline at 3 months*
Full-occlusion biofeedback splint	At 1 month: -5.1 seconds At 3 months: -5.2 seconds	At 1 month: -2.4 At 3 months: 2.2	-50%
Adjusted occlusal splint	At 1 month: 40.1 seconds At 3 months: 11.5 seconds	At 1 month: 4.5 At 3 months: 1.8	7%
p value	At 1 month:.014 At 3 months:.060	At 1 month:.281 At 3 months:.730	.017

RCT: randomized controlled trial.

Table 12. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Bergmann et al (2020)[37,]				5. Clinically significant difference in number/duration of bruxism events not defined	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 13. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Bergmann et al (2020)[37,]		1, 2. Patients, therapists, and analysts were not blinded		1. Several patients in each group had corrupt data due to technical problems with the splints and were classified as lost to follow-up for that reason	1. Power calculations not reported.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Sleep Bruxism

For individuals with sleep bruxism who receive biofeedback, the evidence includes 2 systematic reviews and an RCT published after the review. One systematic review identified 7 randomized and nonrandomized studies using biofeedback techniques, and the most recent systematic review identified 6 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. An RCT published after the reviews tested a full-occlusion biofeedback splint in 41 patients with sleep bruxism and temporomandibular disorder. The trial found that, compared to an adjusted occlusal splint, the biofeedback splint allowed for greater reductions in pain after 3 months of treatment. However, no significant differences in sleep bruxism episodes were observed.

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 individuals with tinnitus.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with tinnitus.

Interventions

The therapy being considered is biofeedback.

Comparators

The following practices are currently being used to treat tinnitus: standard of care.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and QOL. Follow-up at 3 months 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.
- Studies with larger sample sizes were preferred.

Review of Evidence

Randomized Controlled Trials

An RCT by Weise et al (2008) investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany.[38,] 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

For individuals with tinnitus who receive biofeedback, the evidence includes a single RCT. 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.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology

As of October 2023, 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.

American College of Cardiology

In 2017, the American College of Cardiology et al. guidelines on hypertension in adults state that "behavioral therapies, including….biofeedback, lack strong evidence for their long-term BP [blood pressure]-lowering effect."[39,]

American College of Obstetricians and Gynecologists

As of October 2023, 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.

American Heart Association and American Stroke Association

In 2016, the American Heart Association and the American Stroke Association guidelines on adult stroke rehabilitation and recovery state that the usefulness of biofeedback during gait training in patients after stroke is uncertain.[40,]

American Psychiatric Association

The American Psychiatric Association (APA) guidelines on the treatment of major depressive disorder (MDD) have not been updated since 2010, and the APA guidelines on acute stress disorder and posttraumatic stress disorder (PTSD) have not been updated since 2004. These guidelines are classified as "legacy guidelines" by the organization, meaning that they can no longer be assumed to be current. The APA (2010) guidelines on the treatment of patients with MDD did not list biofeedback as a potential treatment.[41,]

In 2004, the APA guidelines on the treatment of patients with acute stress disorder and PTSD mentioned the use of biofeedback to augment relaxation techniques.[42,] 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 Psychological Association

As of October 2023, the American Psychological Association has made no recommendations regarding the use of biofeedback for depression, anxiety, or PTSD.

Global Initiative for Asthma

As of October 2023, the Global Initiative for Asthma guidelines make no recommendations regarding the use of biofeedback for asthma.[43,]

U.S. Department of Veterans Affairs/Department of Defense

As of October 2023, clinical practice guidelines from the U.S. Department of Veterans Affairs and the Department of Defense do not make recommendations on the use of biofeedback for PTSD, motor dysfunction in the limbs after stroke, hypertension, or asthma.[44,]The 2022 guidelines for the management of MDD state that 'for patients with MDD, there is insufficient evidence to recommend for or against the addition of biofeedback."[45,]

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."[46,]

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 14.

Table 14. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04138680	Real-time Biofeedback With 7-Tesla MRI for Treatment of Depression	60	Dec 2023

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04411303	A Novel, Comprehensive Approach to Post-stroke Gait Rehabilitation	50	Dec 2023
Unpublished			
NCT04777253	Effectiveness of Biofeedback Methods in Rehabilitation of Arm Function in Patients After Stroke	100	Dec 2021
NCT02998502	Efficacy of a Biofeedback Breathing System for Anxiety and Panic Disorders	73	Feb 2021
NCT03975075	Biofeedback Treatment of Anxiety Associated With Chronic Spinal Cord Injury	30	Jan 2023

NCT: national clinical trial.

References

1. Goessl VC, Curtiss JE, Hofmann SG. The effect of heart rate variability biofeedback training on stress and anxiety: a meta-analysis. Psychol Med. Nov 2017; 47(15): 2578-2586. PMID 28478782
2. Banerjee S, Argaez C. Neurofeedback and Biofeedback for Mood and Anxiety Disorders: A Review of Clinical Effectiveness and Guidelines [Internet]. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health; 2017.
3. Chen YF, Huang XY, Chien CH, et al. The Effectiveness of Diaphragmatic Breathing Relaxation Training for Reducing Anxiety. Perspect Psychiatr Care. Oct 2017; 53(4): 329-336. PMID 27553981
4. Yorke J, Fleming S, Shuldham C, et al. Nonpharmacological interventions aimed at modifying health and behavioural outcomes for adults with asthma: a critical review. Clin Exp Allergy. Dec 2015; 45(12): 1750-64. PMID 25675860
5. Meuret AE, Ritz T, Wilhelm FH, et al. Targeting pCO(2) in asthma: pilot evaluation of a capnometry-assisted breathing training. Appl Psychophysiol Biofeedback. Jun 2007; 32(2): 99-109. PMID 17564826
6. Lehrer PM, Vaschillo E, Vaschillo B, et al. Biofeedback treatment for asthma. Chest. Aug 2004; 126(2): 352-61. PMID 15302717
7. Lehrer P, Carr RE, Smetankine A, et al. Respiratory sinus arrhythmia versus neck/trapezius EMG and incentive inspirometry biofeedback for asthma: a pilot study. Appl Psychophysiol Biofeedback. Jun 1997; 22(2): 95-109. PMID 9341966
8. Taghizadeh N, Eslaminejad A, Raoufy MR. Protective effect of heart rate variability biofeedback on stress-induced lung function impairment in asthma. Respir Physiol Neurobiol. Apr 2019; 262: 49-56. PMID 30695733
9. Lehrer PM, Irvin CG, Lu SE, et al. Heart Rate Variability Biofeedback Does Not Substitute for Asthma Steroid Controller Medication. Appl Psychophysiol Biofeedback. Mar 2018; 43(1): 57-73. PMID 29124506
10. Cardoso JR, Teixeira EC, Moreira MD, et al. Effects of exercises on Bell's palsy: systematic review of randomized controlled trials. Otol Neurotol. Jun 2008; 29(4): 557-60. PMID 18520590
11. Neurofeedback and Biofeedback for Mood and Anxiety Disorders: A Review of the Clinical Evidence and Guidelines - An Update. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health; 2014.
12. Maynart WHDC, Albuquerque MCDS, Santos RCS, et al. The use of biofeedback intervention in the improvement of depression levels: a randomised trial. Acta Neuropsychiatr. Jun 2021; 33(3): 126-133. PMID 33427129
13. Park SM, Jung HY. Respiratory sinus arrhythmia biofeedback alters heart rate variability and default mode network connectivity in major depressive disorder: A preliminary study. Int J Psychophysiol. Dec 2020; 158: 225-237. PMID 33148502

14. Greenhalgh J, Dickson R, Dundar Y. The effects of biofeedback for the treatment of essential hypertension: a systematic review. Health Technol Assess. Oct 2009; 13(46): 1-104. PMID 19822104
15. Wang MY, Chang NC, Hsieh MH, et al. Effect of Feedback Signal on Blood Pressure Self-regulation Capability in Individuals With Prehypertension or Stage I Hypertension: A Randomized Controlled Study. J Cardiovasc Nurs. 2016; 31(2): 166-72. PMID 25774838
16. Mengden T, Bachler M, Sehnert W, et al. Device-guided slow breathing with direct biofeedback of pulse wave velocity - acute effects on pulse arrival time and self-measured blood pressure. Blood Press Monit. Feb 01 2023; 28(1): 52-58. PMID 36606480
17. Stanton R, Ada L, Dean CM, et al. Biofeedback improves performance in lower limb activities more than usual therapy in people following stroke: a systematic review. J Physiother. Jan 2017; 63(1): 11-16. PMID 27989731
18. Stanton R, Ada L, Dean CM, et al. Biofeedback improves activities of the lower limb after stroke: a systematic review. J Physiother. 2011; 57(3): 145-55. PMID 21843829
19. Zijlstra A, Mancini M, Chiari L, et al. Biofeedback for training balance and mobility tasks in older populations: a systematic review. J Neuroeng Rehabil. Dec 09 2010; 7: 58. PMID 21143921
20. Ambrosini E, Peri E, Nava C, et al. A multimodal training with visual biofeedback in subacute stroke survivors: a randomized controlled trial. Eur J Phys Rehabil Med. Feb 2020; 56(1): 24-33. PMID 31556542
21. Ghanbari Ghoshchi S, De Angelis S, Morone G, et al. Return to Work and Quality of Life after Stroke in Italy: A Study on the Efficacy of Technologically Assisted Neurorehabilitation. Int J Environ Res Public Health. Jul 20 2020; 17(14). PMID 32698430
22. Kim JH. The effects of training using EMG biofeedback on stroke patients upper extremity functions. J Phys Ther Sci. Jun 2017; 29(6): 1085-1088. PMID 28626331
23. Yang DJ. Influence of biofeedback weight bearing training in sit to stand to sit and the limits of stability on stroke patients. J Phys Ther Sci. Nov 2016; 28(11): 3011-3014. PMID 27942111
24. Ghomashchi H. Investigating the effects of visual biofeedback therapy on recovery of postural balance in stroke patients using a complexity measure. Top Stroke Rehabil. Jun 2016; 23(3): 178-83. PMID 27077976
25. Silkman C, McKeon J. The effectiveness of electromyographic biofeedback supplementation during knee rehabilitation after injury. J Sport Rehabil. Aug 2010; 19(3): 343-51. PMID 20811082
26. Xie YJ, Wang S, Gong QJ, et al. Effects of electromyography biofeedback for patients after knee surgery: A systematic review and meta-analysis. J Biomech. May 07 2021; 120: 110386. PMID 33794414
27. Mackay AM, Buckingham R, Schwartz RS, et al. The Effect of Biofeedback as a Psychological Intervention in Multiple Sclerosis: A Randomized Controlled Study. Int J MS Care. 2015; 17(3): 101-8. PMID 26052255
28. van der Logt RP, Findling O, Rust H, et al. The effect of vibrotactile biofeedback of trunk sway on balance control in multiple sclerosis. Mult Scler Relat Disord. Jul 2016; 8: 58-63. PMID 27456875
29. Gillis DJ, Wouda M, Hjeltnes N. Non-pharmacological management of orthostatic hypotension after spinal cord injury: a critical review of the literature. Spinal Cord. Oct 2008; 46(10): 652-9. PMID 18542098
30. Barragán Loayza IM, Solà I, Juandó Prats C. Biofeedback for pain management during labour. Cochrane Database Syst Rev. Jun 15 2011; (6): CD006168. PMID 21678353
31. Wahbeh H, Senders A, Neuendorf R, et al. Complementary and Alternative Medicine for Posttraumatic Stress Disorder Symptoms: A Systematic Review. J Evid Based Complementary Altern Med. Jul 2014; 19(3): 161-175. PMID 24676593
32. Siepmann M, Hennig UD, Siepmann T, et al. The effects of heart rate variability biofeedback in patients with preterm labour. Appl Psychophysiol Biofeedback. Mar 2014; 39(1): 27-35. PMID 24271650
33. Malenfant D, Catton M, Pope JE. The efficacy of complementary and alternative medicine in the treatment of Raynaud's phenomenon: a literature review and meta-analysis. Rheumatology (Oxford). Jul 2009; 48(7): 791-5. PMID 19433434

34. Comparison of sustained-release nifedipine and temperature biofeedback for treatment of primary Raynaud phenomenon. Results from a randomized clinical trial with 1-year follow-up. Arch Intern Med. Apr 24 2000; 160(8): 1101-8. PMID 10789602
35. Wang LF, Long H, Deng M, et al. Biofeedback treatment for sleep bruxism: a systematic review. Sleep Breath. May 2014; 18(2): 235-42. PMID 23756884
36. Jokubauskas L, Baltrušaitytė A. Efficacy of biofeedback therapy on sleep bruxism: A systematic review and meta-analysis. J Oral Rehabil. Jun 2018; 45(6): 485-495. PMID 29577362
37. Bergmann A, Edelhoff D, Schubert O, et al. Effect of treatment with a full-occlusion biofeedback splint on sleep bruxism and TMD pain: a randomized controlled clinical trial. Clin Oral Investig. Nov 2020; 24(11): 4005-4018. PMID 32430774
38. Weise C, Heinecke K, Rief W. Biofeedback-based behavioral treatment for chronic tinnitus: results of a randomized controlled trial. J Consult Clin Psychol. Dec 2008; 76(6): 1046-57. PMID 19045972
39. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. Oct 23 2018; 138(17): e426-e483. PMID 30354655
40. Winstein CJ, Stein J, Arena R, et al. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. Jun 2016; 47(6): e98-e169. PMID 27145936
41. Gelenberg A. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. 2010; https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed October 2, 2023.
42. American Psychiatric Association, Work Group on ASD and PTSD, Ursano RJ, et al. Practice Guideline for the Treatment of Patients with Acute Stress Disorder and Posttraumatic Stress Disorder. 2004; http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/acutestressdisorderptsd.pdf. Accessed October 2, 2023.
43. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. 2023; https://ginasthma.org/2023-gina-main-report/. Accessed October 2, 2023.
44. U.S. Department of Veterans Affairs. VA/DoD Clinical Practice Guidelines. Updated September 28, 2023; https://www.healthquality.va.gov/. Accessed October 2, 2023.
45. U.S. Department of Veterans Affairs. VA/DoD Clinical Practice Guidelines for the management of major depressive disorder. 2022; https://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFinal508.pdf. Accessed October 3, 2023.
46. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Biofeedback (30.1). n.d.; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=41. Accessed October 2, 2023.

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.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

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
	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: • 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.
02/01/2024	Policy reactivated. Previously archived from 09/01/2020 to 01/31/2024.

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 and Feedback (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.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
Reactivated Policy **Policy Statement:** N/A	**Biofeedback for Miscellaneous Indications 2.01.53** **Policy Statement:** I. Biofeedback is considered **investigational** as a treatment of the following miscellaneous conditions: A. Anxiety disorders B. Asthma C. Bell palsy D. Depression E. Hypertension F. Insomnia G. Movement disorders, such as motor function after stroke, injury, or lower-limb surgery H. Multiple sclerosis I. Orthostatic hypotension in individuals with spinal cord injury J. Pain management during labor K. Posttraumatic stress disorder L. Prevention of preterm birth M. Raynaud disease N. Sleep bruxism O. Tinnitus