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Biofeedback for Miscellaneous Indications

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Related Policies (if applicable)
PSY301.016 Biofeedback as a Treatment of Urinary Incontinence None
PSY301.017 Biofeedback as a Treatment of Fecal Incontinence or Constipation
PSY301.018 Biofeedback as a Treatment of Chronic Pain
PSY301.019 Biofeedback as a Treatment of Headache
MED205.022 Treatment of Tinnitus

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

NOTE 1: HCSC medical policies on biofeedback for specific indications supersede use of this policy.

Biofeedback **is considered experimental, investigational and/or unproven** to treat a variety of conditions, including but not limited to:

- Anxiety disorders
- Asthma
- Bell's palsy
- Depression
- Hypertension
- Insomnia
- Movement disorders, such as motor function after stroke, injury, or lower-limb surgery
- Multiple sclerosis

- Orthostatic hypotension in individuals with spinal cord injury
- Pain management during labor
- Posttraumatic stress disorder
- Prevention of preterm birth
- Raynaud's disease
- Sleep bruxism.

Policy Guidelines

None.

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 medical policy focuses on the use of biofeedback for treating miscellaneous indications - specifically, indications other than urinary and fecal incontinence, headache, and chronic pain.

Background

Biofeedback is a technique intended to teach patients 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 policy focuses on the use of biofeedback for the treatment of hypertension, anxiety, insomnia, asthma, movement disorders (e.g., motor function after stroke, injury, or lower-limb surgery), and other miscellaneous applications (i.e., conditions not addressed in other medical policies on biofeedback).

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

Regulatory Status
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

This medical policy was created in September 1990 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through September 30, 2021.

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

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

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

Anxiety Disorders

Clinical Context and Therapy Purpose

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

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

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

Populations
The relevant population of interest is 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 eight weeks is of interest to monitor outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

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

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

The Canadian Agency for Drugs and Technology in Health (2014) published a rapid response report on biofeedback for treating mood and anxiety disorders. (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 (DBR) with routine respiration activities in the treatment of 46 patients with anxiety. (3) DBR is a technique that uses diaphragm muscle contractions to force air downward into the body, increasing diaphragm length and breathing efficiency. Outcomes were anxiety level, measured by the Beck Anxiety Inventory, and four physiological measures (skin conductivity, peripheral blood flow, heart rate, breathing rate). All patients participated in an individualized 8-week course in breathing relaxation, but only 30 completed it. Fifteen were randomized to DBR training and 15 to routine breathing relaxation training. Researchers and patients were blinded to randomization, with only the trainer being aware of group allocation. After eight weeks, the DBR group experienced statistically significant decreases in Beck Anxiety Inventory scores compared with baseline, while the control group did not. The DBR group also experienced significant improvements in all four physiological measurements, while the control group did not.

Section Summary: Anxiety Disorders

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 patients with asthma.

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

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

Populations

The relevant population of interest is 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.

Systematic Reviews
Yorke et al. (2015) published a systematic review of studies 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 (FEV1) were found and medication use decreased in only 1 trial. Reviewers concluded that larger sample sizes were needed to demonstrate effects and that, while certain parameters that patients received biofeedback on may have differed between treatment groups, those differences did not translate into meaningful clinical benefits.

Randomized Controlled Trials
Taghizadeh et al. (2019) hypothesized that heart rate variability biofeedback (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 four groups were statistically significantly stressed ($p < .001$). Although the healthy group who underwent HRVB reported significantly less stress than the healthy control group ($p = .034$), the participants with asthma did not experience this effect. In fact, larger stress induced HRV changes suggested an exaggerated response in asthmatic participants compared to the healthy ones. However, spirometry parameters, which were monitored throughout the experimental procedures, showed that HRVB had a protective effect on the participants with asthma as well as enhanced the level of forced expiratory volume percent ($p = 0.002$) and forced vital capacity percent ($p < 0.001$) as compared to baseline. The authors concluded that HRVB is a promising protective approach to aid lung function and reduce asthma exacerbation caused by stress. Some limitations of the study include using only the Stroop test to induced stress, measuring stress on a subjective visual analog scale, and including only female participants.

Lehrer et al. (2018) examined the efficacy and safety of HRVB on asthma to determine if the treatment could substitute for the controller or rescue medication and whether HRVB controls airway inflammation. (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 quality of life, 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 patients with information on carbon dioxide, heart rate, and respiratory sinus arrhythmia. While the trials reported improvements in each parameter for which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. However, 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 patients with Bell palsy.

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

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

Populations
The relevant population of interest is 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. Treatment and follow-up over 1 to 12 months are of interest to monitor outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the 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.

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 vs control (n=50 patients), mirror biofeedback exercise vs control (n=27 patients), "small" mirror movements vs conventional neuromuscular retraining (n=10 patients), and EMG biofeedback plus mirror training vs mirror training alone. The treatment length varied from 1 to 12 months. Reviewers concluded that, given the paucity of RCTs, the current evidence does not support the use of biofeedback to treat this population.

Section Summary: Bell Palsy
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 patients with depression.

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

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

Populations

The relevant population of interest is 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 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.

Systematic Reviews

The Canadian Agency for Drugs and Technology in Health (2014) report on biofeedback for mood and anxiety disorders (previously discussed in the Anxiety section), (2) included a systematic review of the literature on biofeedback for depression. Other than two dissertations using HRV biofeedback, no health technology assessments, systematic reviews, meta-analyses,

RCTs, or nonrandomized studies evaluating biofeedback for the treatment of depression were identified.

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. (11) 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. (12) 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) (11)	Brazil	3	NR	Adults aged 18 years or older with major depressive disorder or dysthymia treated with antidepressants and BDI score of 20 to 63	Respiratory rate and blood volume pulse/heart rate biofeedback plus usual care (n=18)	Usual care alone (n=18)
Park and Jung (2020) (12)	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 (11)		*% 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 along	NR	Minimum: 2.8% Light: 13.9% Moderate: 30.6% Severe: 2.8%
p value	NR	.046
Park and Jung (2020) (12)	*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 (11)			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) (12)			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 literature 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 (11)		1,2. Open label design			1. Power calculations not detailed	
Park and Jung (2020) (12)		1,2. Open label design				

The study limitations stated in this table are those notable in the current literature 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 only identified 2 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 patients with hypertension.

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

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

Populations

The relevant population of interest is 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 six 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.

Systematic Reviews

A systematic review of studies on biofeedback for hypertension was published by Greenhalgh et al. in 2009. (13) Reviewers searched for RCTs that included adults with essential hypertension (defined as at least 140/90 mm Hg) and that compared biofeedback interventions, alone or in combination, with other therapies, to medication, sham biofeedback, no treatment, or another behavioral intervention. Thirty-six trials (total N=1660 patients) met inclusion criteria. Trials generally had small sample sizes; only 4 included more than 100 patients. All were single-center, and most were conducted in the United States. Trials used a variety of biofeedback techniques including thermal biofeedback, galvanized skin response,

pulse wave velocity, and HRV; some trials used more than one modality. Twenty studies evaluated biofeedback alone, 15 evaluated biofeedback combined with another intervention, and one had multiple arms and evaluated both types of interventions; only four 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 one trial compared a biofeedback combination intervention with sham biofeedback, and it did not find a significant difference in the efficacy of the two interventions. Four studies on biofeedback alone and another four on a combined biofeedback intervention reported data beyond 6 months; most of them found no significant differences in efficacy between the biofeedback and control groups.

Randomized Controlled Trials

Wang et al. (2016) published an RCT evaluating the effect of direct blood pressure biofeedback on patients with prehypertension or stage I hypertension. (14) A trained nurse instructed patients in blood pressure self-regulation by using slow diaphragmatic breathing and passive attitude. During the 8-week training (1 session per week), patients in the treatment group received real-time blood pressure feedback signals (n=29) and controls received pseudo-feedback signals (n=28). Outcomes were systolic and diastolic blood pressure, measured at baseline and one and eight weeks after training. Both groups significantly decreased blood pressure following training. The decreases were equal in magnitude, suggesting that blood pressure self-regulation training can effectively lower blood pressure, regardless of the type of feedback signal.

Section Summary: Hypertension

For individuals with hypertension who receive biofeedback, the evidence includes a systematic review and an RCT 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.

Motor Dysfunction After Stroke

Clinical Context and Therapy Purpose

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

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

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

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

Interventions
The therapy being considered is biofeedback.

Comparators
The following practices are currently being used to treat stroke-related motor dysfunction: 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.

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. (15-16) Only high-quality RCTs or quasi-RCTs with Physiotherapy Evidence Database scores greater than four were included. Training activities were walking (nine trials), standing (eight trials), and standing up (one trial). Biofeedback techniques included weight distribution from a force platform or sensor (11 trials), muscle activity from EMG (3 trials), linear gait parameters (3 trials), and joint angle from a goniometer (1 trial). Visual feedback was used in seven trials, auditory in seven trials, and a combination of visual and auditory in four trials. The pooled standardized mean difference of the short-term effect of biofeedback from 17 trials (n=417) was significant (0.50; 95% confidence interval [CI], 0.3 to 0.7). Long-term effects could not be calculated because only four trials provided that information.

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

Table 5 summarizes the characteristics of selected systematic reviews.

Table 5. Characteristics of the Systematic Review

Study	Dates	Trials	Participants[1]	N (Range)	Design	Duration
Stanton el al. (2017) (15)	To 2015	18	Lower-limb motor function loss poststroke	429 (12-50)	RCTs	NR
Zijlstra et al. (2010) (17)	1993-2012	21	Patients >60 y receiving biofeedback to improve motor function	NR (5-30)	17 RCTs, 4 other	NR

NR: not reported; RCT: randomized controlled trials.

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. (18) 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. (19) 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. (20) 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. (21) 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. (22) 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.	Italy	1	2015-2018	Adults aged 18 to 90 years in an inpatient	20 minutes of visual biofeedback	90 minutes of usual care per session; 30

(2020) (18)				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	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)	sessions (n=34)
Ghanbari Ghoshchi et al. (2020) (19)	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	FIM	Berg Balance Test	Modified Barthel Index	Return to work	Fall events
Ambrosini et al. (2020) (18)	*Change from baseline to post*	*Change from baseline to post*	*Change from baseline to post treatmen*	*Change from baseline to post*			

	treatment	*treatment*	*t in the motor subscale*	*treatment*			
Biofeedback	27.7 cm/s	110.2m	35	21	NR	NR	NR
Usual care	21.3cm/s	76.1m	31	18	NR	NR	NR
p value	.305	.120	.451	.211	NR	NR	NR
Ghanbari Ghoshchi et al. (2020) (19)						*At 6 month follow up*	*At 6 month follow up*
Technological rehabilitation with biofeedback	NR	NR	NR	NR	Postreha b: 88 6-month follow up: 100	11 (47.8%)	5 (21.7%)
Con-ventional rehabilitation	NR	NR	NR	NR	Postreha b: 80 6-month follow up: 95	9 (36.0%)	4 (16.0%)
p value	NR	NR	NR	NR	Postreha b: 391 6-month follow up: 450	.406	.611

NR: not reported; RCT: randomized controlled trial; FIM: functional independence measure.

Table 8. Study Relevance Limitations

Study	Population[a]	Internention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Ambrosini et al. (2020) (18)					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) (19)					

The study limitations stated in this table are those notable in the current literature 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) (18)		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) (19)		1. Single-blind design (patients not blinded)			1. Power cal-culations not reported	

The study limitations stated in this table are those notable in the current literature 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 Lover-Limb Injury or Surgery

Clinical Context and Therapy Purpose

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

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

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

Populations

The relevant population of interest is 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: 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 symptoms would typically occur in the months to years after starting treatment.

Study Selections 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.

Systematic Reviews

A systematic review by Silkman and McKeon (2010) evaluated the effectiveness of EMG biofeedback for improving muscle function during knee rehabilitation after injury. (23) Four RCTs that compared knee rehabilitation exercise programs with and without biofeedback were identified. Sample sizes in individual studies ranged from 26 to 60 patients. Two of the four studies found a statistically significantly greater benefit in the programs that included biofeedback, while the others did not. The positive studies assessed intermediate outcomes (e.g., contraction values of the quadriceps muscles). None of the studies were designed to assess functional outcomes.

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. (24) 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 (MS)

Clinical Context and Therapy Purpose

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

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

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

Populations

The relevant population of interest is individuals with MS.

Interventions

The therapy being considered is biofeedback.

Comparators

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

Outcomes

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

Study Selection Criteria

Methodologically credible studies were selected using the 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.

Randomized Controlled Trials

An RCT by MacKay et al. (2015) evaluated the addition of biofeedback to standard care in 40 patients with relapsing-remitting MS patients. (25) The standard of care psychosocial intervention consisted of relaxation, mindfulness, social support, and education. All patients attended one-hour training and assessment sessions at weekly intervals. During the first session, all patients had training in mindfulness breathing exercises and progressive muscle relaxation techniques. Patients randomized to the biofeedback arm received additional instruction on the use of biofeedback equipment for self-regulation. Following the three weekly sessions, patients were instructed to practice the exercises at home, with or without the use of biofeedback equipment. Outcomes included breathing rate and anxiety, depression, fatigue, and muscle tension measures. At the end of treatment, there were no statistically significant differences between groups in any outcomes. For example, the differences between the intervention group and the control group in breathing rate were 3.06 beats per minute (95% CI, -0.17 to 6.28 beats per minute; p=0.06) and the difference in muscle tension was -13.91 μV (95% CI, -30.06 to 2.25 μV; p=0.09). Both groups received similar amounts of provider contact, so nonspecific intervention effects were not an issue.

A crossover study by van der Logt et al. (2016) evaluated the effect of vibrotactile biofeedback for trunk sway on balance control in patients with multiple sclerosis. (26) 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 patients with orthostatic hypotension due to spinal cord injury.

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

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

Populations

The relevant population of interest is 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: 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 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.

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. (27) Participants with any level or degree of completeness of spinal cord injury and any time elapsed since their injuries were included. Interventions must have measured at least systolic blood pressure and have induced orthostatic stress in a controlled manner and have attempted to control orthostatic hypotension during an orthostatic challenge. Thirteen studies (total n=138 patients) were included in the review. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified, and only two studies evaluated biofeedback. These 2 studies, which assessed 3 patients using biofeedback techniques, reported an average of 39% increase in systolic blood pressure. Reviewers concluded that ".... The clinical usefulness of compression/pressure, upper body exercise, and biofeedback for treating OH [orthostatic hypotension] has not been proven."

Section Summary: Orthostatic Hypotension in Patients with Spinal Cord Injury
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 patients who need pain management during labor.

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

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

Populations

The relevant population of interest is women needing 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 for pain management during labor symptoms would typically occur in the days to weeks in the postnatal period.

Study Selection Criteria

Methodologically credible studies were selected using the 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.

Systematic Reviews

In a Cochrane review, Barragan Loayza et al. (2011) evaluated RCTs on the use of biofeedback for managing pain during labor. (28) Reviewers identified 4 RCTs published between 1982 and 2000 (total n=186 women). The studies were highly variable in terms of intervention modalities and outcomes measured, and thus findings were not pooled. In addition, reviewers judged the trials to be at high risk of bias (e.g., unclear description of blinding and randomization

methods). Overall, they found little difference in reported outcomes (e.g., rates of Cesarean section, pharmacologic pain relief in women receiving biofeedback vs control interventions). Due to the small number of studies and small pooled sample size, the evidence did not support drawing conclusions about the effectiveness of biofeedback in labor pain control.

Section Summary: Pain Management During Labor

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 (PTSD)

Clinical Context and Therapy Purpose

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

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

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

Populations

The relevant population of interest is 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 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.

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. (2) One systematic review was identified; in it, Wahbeh et al. (2014) assessed various complementary and alternative medicine approaches to treating PTSD. (29) Four of 33 studies that met the selection criteria of the Wahbeh et al. (2014) review addressed biofeedback. Among the biofeedback studies were one RCT, one nonrandomized trial, and two case series. The controlled trials either had mixed results or did not find a significant benefit of biofeedback. Reviewers gave the biofeedback evidence a grade C for unclear or conflicting scientific evidence.

Section Summary: Posttraumatic Stress Disorder

For individuals with PTSD who receive biofeedback, the evidence includes a systematic review. The 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.

Prevention of Preterm Birth

Clinical Context and Therapy Purpose

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

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

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

Populations

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

Interventions

The therapy being considered is biofeedback.

Comparators

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

Outcomes

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

Study Selection Criteria

Methodologically credible studies were selected using the 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.

Randomized Controlled Trials

Siepmann et al. (2014) published data on 48 female candidates for preterm labor between the 24th and the 32nd gestational week. (30) Twenty-four women received 6 biofeedback sessions over 2 weeks, and the other 24 women received usual care. Preterm delivery occurred in 3 (13%) patients in the biofeedback group and 8 (33%) patients in the control group; the difference between groups was not statistically significant ($p>0.05$). Other gestational outcomes data, such as the gestational duration and birthweight, also did not differ significantly between groups.

Section Summary: Prevention of Preterm Birth

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 heart rate variability biofeedback. Patients receiving the treatment experienced a decrease in perceived chronic stress, but there was no significant difference in the number of preterm births, gestational duration, or birth weight.

Raynaud Disease

Clinical Context and Therapy Purpose

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

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

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

Populations

The relevant population of interest is 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 one 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.

Systematic Reviews
A systematic review by Malenfant et al. (2009) assessed the use of complementary and alternative medicine to treat Raynaud disease. (31) Reviewers identified five trials using biofeedback techniques, and they reported a variety of outcomes. A pooled analysis of findings from 4 trials (n=110 patients) on the change in frequency of attacks (typically extremities feel cold and numb) favored the sham-control group over the biofeedback group (weighted mean difference, -1.21; 95% CI, -1.68 to -0.73; p<0.000). Several trials had more than two arms; in the preceding analysis, only the arms comparing active with sham biofeedback were included.

Randomized Controlled Trials
The trial given the highest quality rating in the Malenfant systematic review and with the largest sample size is the Raynaud's Treatment Study, published in 2000. (32) This randomized trial compared sustained release nifedipine with thermal biofeedback in 313 patients with primary Raynaud disease. In addition to these two treatment groups, there were two control treatments: pill placebo and EMG biofeedback. EMG biofeedback was chosen as a control because it did not address the physiological mechanism of Raynaud disease. The mean attack rate at 1 year (the primary study outcome) was 0.16 in the thermal biofeedback group, 0.23 in the EMG biofeedback group, 0.07 in the nifedipine group, and 0.21 in the placebo group. Nifedipine significantly reduced Raynaud attacks compared with placebo (p<0.002), but thermal feedback did not differ significantly from EMG biofeedback (0.37). There was no significant difference between attack rates in the nifedipine and thermal biofeedback groups for the primary outcome (p=0.08).

Section Summary: Reynaud Disease
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 patients with sleep bruxism.

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

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

Populations

The relevant population of interest is 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. Treatment and follow-up of six weeks are 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.

Systematic Reviews

Wang et al. (2014) published a systematic review of RCTs and non-RCTs evaluating biofeedback treatment for sleep bruxism. (33) Seventeen articles were reviewed, and 7 studies with (total n=240 participants) met the inclusion criteria. Studies were generally small; only 2 included more than 50 participants. Four studies used audio biofeedback, two used contingent electric stimulation, and one used visual biofeedback. Treatment durations ranged from one night to six weeks. In four studies, the treatment duration was two weeks. Three studies at moderate risk of bias, and the other four were considered at high risk of bias. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Only 2

studies (n=27 patients) reported this outcome and had data suitable for meta-analysis. A pooled analysis did not find a statistically significant difference between the biofeedback and control groups (mean difference, -4.47; 95% CI, -12.33 to 3.38). Findings were not pooled for any other outcomes.

Jokubauskas et al. (2018) updated the systematic review by Wang et al. (2014) (above) on the management of sleep bruxism with biofeedback. (34) Five databases were searched for literature published after the original 2012 search. Six relevant publications were included (total n=86 adults), and of these studies, 4 were RCTs and 2 were uncontrolled before-after studies. For the quantitative synthesis, two additional studies were included from the original Wang et al. (2014) review. Contingent electrical stimulation, audio feedback, and a maxillary biofeedback splint were among the biofeedback techniques investigated, and all studies measured sleep bruxism with EMG with the exception of one, which used a mini wireless biofeedback device that analyzed bite force. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Secondary outcomes of sleep quality and pain-related outcomes were also investigated in the studies, and one study reported on patient-perceived symptom change. Overall, the quality of these studies was assessed as low to moderate due to imprecision and inconsistency between studies, and the risk of bias was graded as high to moderate. Despite the limitations of the studies, the use of biofeedback to treat sleep bruxism has shown some effectiveness and is relatively safe and noninvasive.

Randomized Controlled Trials

One RCT by Bergmann et al. (2020) has been published since the systematic reviews discussed above. (35) 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) (35)	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) (35)	*Mean change from baseline in seconds of bruxism per hour*	*Means 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) (35)				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 literature 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) (35)		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 literature 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.

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

For individuals with asthma who receive biofeedback, the evidence includes 3 RCTs and 2 RCTs published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. Each RCT used a different biofeedback technique, which provided patients with information on carbon dioxide, heart rate, and respiratory sinus arrhythmia. While the trials reported improvements in each parameter for which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. However, the results of one RCT suggested that biofeedback has promise as a protective approach to aiding lung function and reducing stress-induced asthma exacerbation. The evidence is insufficient to determine the effects of technology results in an improvement on net health outcome.

For individuals with Bell palsy who receive biofeedback, the evidence includes a systematic review of four RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCTs evaluated the efficacy of adding a mirror and/or electromyography biofeedback to facial exercises. The sample sizes were small, and there was heterogeneity across techniques used and length of treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with depression who receive biofeedback, the evidence includes a systematic review and 2 small RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The review only identified two dissertations assessing the use of biofeedback for depression. One RCT found that respiratory and heart rate biofeedback plus usual care reduced Beck Depression Inventory (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 Hamilton Depression Rating Scale (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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with hypertension who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. Relevant outcomes are symptoms, functional

outcomes, and quality of life. The systematic review identified 36 RCTs, though sample sizes were small and overall study quality poor. Various biofeedback techniques were used: thermal, galvanized skin response, pulse wave velocity, and heart rate variability (HRV). Results across trials did not consistently show a benefit of biofeedback. Conclusions were limited due to the heterogeneity across interventions and the generally poor quality of the trials. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals with motor dysfunction after lower-limb injury or surgery who receive biofeedback, the evidence includes 2 systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. One systematic review identified four RCTs evaluating the use of electromyography biofeedback in patients undergoing postinjury study groups. The other systematic review identified 6 RCTs evaluating the use of electromyography (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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with multiple sclerosis who receive biofeedback, the evidence includes two RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One trial used vibrotactile biofeedback and the other provided patients with heart rate and muscle tension biofeedback. The sample sizes were small, with no statistically significant differences between the biofeedback groups and control groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. Relevant outcomes are symptoms, functional outcomes, and quality of life. The case series and a case report collectively provided information on three patients given visual and auditory feedback. Patients were able to raise their systolic blood pressure by an average of

39%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who need pain management during labor who receive biofeedback, the evidence includes a systematic review of four RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Due to the heterogeneity in biofeedback methods and outcomes measured, pooled analyses could not be performed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with post-traumatic stress disorder (PTSD) who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The 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 evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

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

Practice Guidelines and Position Statements

American Psychiatric Association

The American Psychiatric Association (APA) guidelines on the treatment of major depressive disorder 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 major depressive disorder did not list biofeedback as a potential treatment. (36)

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. (37) 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 September 2021, the American Psychological Association has made no recommendations regarding the use of biofeedback for depression, anxiety, or PTSD.

American Academy of Neurology

As of September 2021, 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-lowering effect." (38)

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. (39)

American College of Obstetricians and Gynecologists

As of September 2021, 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.

Global Initiative for Asthma

As of September 2021, the Global Initiative for Asthma guidelines make no recommendations regarding the use of biofeedback for asthma. (40)

United States (U.S.) Department of Veterans Affairs/Department of Defense
As of September 2021, 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 depression, PTSD, motor dysfunction in the limbs after stroke, hypertension, or asthma. (41)

United States (U.S.) Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force recommendations for the use of biofeedback have been identified.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this policy are listed in Table 14.

Table 14. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04777253	Effectiveness of Biofeedback Methods in Rehabilitation of Arm Function in Patients After Stroke	100	Oct 2021
NCT02998502	Efficacy of a Biofeedback Breathing System for Anxiety and Panic Disorders	73	Feb 2021 (Completed)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	90875, 90876, 90901
HCPCS Codes	E0746

*Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2024	Reviewed. No changes.
04/15/2022	Document updated with literature review. Coverage unchanged. References 11, 12, 18, 19, 24, 25, 35, 39, 40, and 41 added; others removed.
04/01/2021	Reviewed. No changes.
02/15/2021	Document updated with literature review. The following changes were made to Coverage: 1) Removed tinnitus from the experimental, investigational and/or unproven example list; 2) Added MED205.022 Treatment of Tinnitus to NOTE referencing other biofeedback policies. Reference numbers 9-10, 22, 33 and 40 added; 36 removed.
02/15/2019	Reviewed. No changes.
07/01/2018	Document updated with literature review. Coverage has changed to combine two bullets: “Movement disorders” and “Motor function after stroke, injury, or lower-limb surgery” into one bullet: “Movement disorders, such as motor function after stroke, injury, or lower-limb surgery”. Reference numbers 4-8, 11, 14, 17-19, 21, 31, 33, and 34 were added.
07/15/2017	Document updated with literature review. The following clinical indications: depression, multiple sclerosis and posttraumatic stress disorder, were added to the current experimental, investigational and/or unproven coverage statement.
04/01/2016	Reviewed. No changes.
10/01/2015	Document updated with literature review. Coverage unchanged. Two new examples of conditions, “Pain management during labor” and “Prevention of preterm birth”, were added to the experimental, investigational and/or unproven statement.
12/01/2014	Reviewed. No changes.
02/01/2013	Medical document divided into: PSY301.011, PSY301.016, PSY301.017, PSY301.018, and PSY301.019. Document title changed from “Biofeedback and Neurofeedback”. Document updated with literature review. Biofeedback is considered experimental, investigational and unproven to treat a variety of conditions.
02/15/2009	CPT/HCPCS code(s) updated.
06/15/2007	CPT/HCPCS code(s) updated.
01/01/2006	Medical document combined with PSY301.011 (Neurofeedback). Document title changed. Document updated with literature review.
09/23/2004	Document updated.
01/01/2002	Legislative information added to Coverage and Rationale.
09/01/1998	Document updated.
12/01/1996	Document updated.

09/01/1996	Document updated.
01/01/1996	Document updated.
01/01/1993	Document updated.
04/01/1992	Document updated.
09/01/1991	Document updated.
09/01/1990	New medical document