

2.01.28	Neurofeedback		
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Section:	2.0 Medicine	Page:	Page 1 of 27

Policy Statement

- I. Neurofeedback is considered **investigational**.

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

Policy Guidelines

Coding

Neurofeedback is specific to electroencephalogram (EEG) biofeedback. There is no specific CPT code for neurofeedback.

The following CPT codes may be used to describe neurofeedback:

- **90875:** Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
- **90876:** Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
- **90901:** Biofeedback training by any modality

Description

Neurofeedback describes techniques for providing feedback about neuronal activity, as measured by electroencephalogram biofeedback, functional magnetic resonance imaging, or near-infrared spectroscopy, to teach patients to self-regulate brain activity. Neurofeedback may use several techniques in an attempt to normalize unusual patterns of brain function in patients with various psychiatric and central nervous system disorders.

Related Policies

- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback as a Treatment of Headache
- Biofeedback as a Treatment of Urinary Incontinence in Adults
- Biofeedback for Miscellaneous Indications
- Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder

Benefit Application

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

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

Regulatory Status

A number of EEG feedback systems (EEG hardware and computer software programs) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. For example, the BrainMaster™ 2E (BrainMaster Technologies) is "...indicated for relaxation training using alpha EEG Biofeedback. In the protocol for relaxation, BrainMaster™ provides a visual and/or auditory signal that corresponds to the patient's increase in alpha activity as an indicator of achieving a state of relaxation." Although devices used during neurofeedback may be subject to FDA regulation, the process of neurofeedback itself is a procedure, and, therefore, not subject to the FDA approval. FDA product codes: HCC, GWQ.

Rationale

Background

Disorders of the Central Nervous System

Various of disorders involve abnormal brain activity, including autism spectrum disorder, insomnia and sleep disorders, learning disabilities, Tourette syndrome, traumatic brain injury, seizure disorders, premenstrual dysphoric disorder, menopausal hot flashes, depression, stress management, panic and anxiety disorders, posttraumatic stress disorder, substance abuse disorders, eating disorders, migraine headaches, stroke, Parkinson disease, fibromyalgia, tinnitus, and attention-deficit/hyperactivity disorder.

Treatment

Neurofeedback is being investigated for the treatment of a variety of disorders. Neurofeedback may be conceptualized as a type of biofeedback that has traditionally used the electroencephalogram (EEG) as a source of feedback data. Neurofeedback differs from established forms of biofeedback in that the information fed back to the patient (via EEG tracings, functional magnetic resonance imaging, near-infrared spectroscopy) is a direct measure of global neuronal activity, or brain state, compared with feedback of the centrally regulated physiologic processes, such as tension of specific muscle groups or skin temperature. The patient may be trained to increase or decrease the prevalence, amplitude, or frequency of specified EEG waveforms (e.g., alpha, beta, theta waves), depending on the changes in brain function associated with the particular disorder. It has been proposed that training of slow cortical potentials (SCPs) can regulate cortical excitability and that using the EEG as a measure of central nervous system functioning can help train patients to modify or control their abnormal brain activity. Upregulating or downregulating neural activity with real-time feedback of functional magnetic resonance imaging signals is also being explored.

Two EEG-training protocols (training of SCPs, theta/beta training) are typically used in children with attention-deficit/hyperactivity disorder. For training of SCPs, surface-negative and surface-positive SCPs are generated over the sensorimotor cortex. Negative SCPs reflect increased excitation and occur during states of behavioral or cognitive preparation, while positive SCPs are thought to indicate a reduction of cortical excitation of the underlying neural networks and appear during behavioral inhibition. In theta/beta training, the goal is to decrease activity in the EEG theta band (4-8 Hz) and increase activity in the EEG beta band (13-20 Hz), corresponding to an alert and focused but relaxed state. Alpha-theta neurofeedback is typically used in studies on substance abuse. Neurofeedback protocols for depression focus on alpha interhemispheric asymmetry and theta/beta ratio within the left prefrontal cortex. Neurofeedback for epilepsy has focused on sensorimotor rhythm up-training (increasing 12-15 Hz activity at motor strip) or altering SCPs. It has been

proposed that learned alterations in EEG patterns in epilepsy are a result of operant conditioning and are not conscious or voluntary. A variety of protocols have been described for treatment of migraine headaches.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, 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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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

Attention-Deficit/Hyperactivity Disorder

Clinical Context and Therapy Purpose

The purpose of neurofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as behavioral therapy and pharmacologic therapy, in individuals with attention-deficit/hyperactivity disorder (ADHD). The following PICO was used to select literature to inform this review.

Population

The relevant population of interest is individuals with ADHD. Attention deficit hyperactivity disorder manifests in children as symptoms of hyperactivity, impulsivity, and/or inattention, and affects cognitive, academic, behavioral, emotional, and social function.¹ It is one of the most common neurobehavioral disorders of childhood.

Interventions

The therapy being considered is neurofeedback. Neurofeedback describes techniques for providing feedback about neuronal activity, as measured by electroencephalogram (EEG) biofeedback, functional magnetic resonance imaging, or near-infrared spectroscopy, to teach patients to self-regulate brain activity. Neurofeedback may use several techniques to normalize unusual patterns of brain function in patients with various psychiatric and central nervous system disorders.

Comparators

Guidelines for treatment of ADHD in children and adolescents generally recommend parent training in behavior management, US Food and Drug Administration (FDA)-approved medications (e.g., stimulants), and educational interventions. ADHD also occurs in adults, with a prevalence of approximately 3.4% to 4.4% of US adults. Guidelines for the treatment of ADHD in adults include recommendations for psychoeducation, pharmacotherapy, and cognitive behavioral therapy.² Comparators of interest include behavioral therapy and pharmacologic therapy. Treatment includes support groups, cognitive behavioral therapy, anger management, counseling, psychology, psychoeducation, family therapy, and applied behavior analysis. Medications for treatment include stimulants, cognition-enhancing medication, and antihypertensive drugs.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life (Tables 1 and 2).

Table 1. Outcomes of Interest for Individuals with ADHD

Outcomes	Details
Symptoms	Outcomes as reported by assessors (parents most-often, or teachers, usually unblinded and with a high risk of bias); Attention Deficit Hyperactivity Disorder-Rating Scale (ADHS-RS, domains of inattention, hyperactivity/impulsiveness, and combined scores); Conners scale; Fremdbeurteilungsbogen für Hyperkinetische Störungen (FBB-HKS) [Timing: greater than 1 year]

ADHD: attention-deficit/hyperactivity disorder.

Table 2. Health Outcome Measures Relevant to ADHD in Children and Adolescents

Outcome	Measure (units)	Description	Clinically Meaningful Difference (If Known)
Attention-Deficit/Hyperactivity Disorder-Rating Scale (ADHD-RS)	Scale from 0 to 54 Higher scores indicate more symptoms 18 items are grouped into 2 subscales: hyperactivity/impulsivity and inattentiveness	Short scale that can be completed by parent, teacher, or investigator based on information provided by teacher or parent	Change between 5.2 and 7.7 points or 30% mean total score change between treatment groups ³ .
Conners Parent Rating Scale for ADHD	Scale from 0 to 144 Higher scores indicate more symptoms	Used by clinicians and researchers to assess parents' perception of children's behavior in the classroom Assesses conduct problems, learning problems, psychometric problems, impulsivity and hyperactivity, and anxiety	Not defined ³ .
Conners 3rd Edition-Parent (Conners 3-P)	Scale with 9 subscales Higher scores indicate more symptoms	Used by parents to assess symptoms of ADHD and common comorbid problems	Not defined
Fremdbeurteilungsbogen für Hyperkinetische Störungen (FBB-HKS)	Scale with 20 items	Items can be rated by parents or teacher	Not defined

Outcome	Measure (units)	Description	Clinically Meaningful Difference (If Known)
	Higher scores indicate more symptoms		

ADHD: attention-deficit/hyperactivity disorder.

In studies of neurofeedback, the duration of intervention was at least 1 month and ranged from 1 to 12 months.^{4,5,6} Follow-up studies of RCTs that reported longer-term outcomes have reported results at 6 months.^{7,8}

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
- Within each category of study design, studies with larger sample sizes and longer duration were preferred;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews with Meta-Analysis

Numerous systematic reviews with meta-analyses have compared neurofeedback versus other treatments for ADHD in children, adolescents, and adults (Tables 3 to 5).^{9,5,6,4,10} Comparators included methylphenidate, biofeedback, cognitive behavioral therapy, cognitive training, or physical activity. The results of these analyses generally demonstrated either small to moderate or no benefit of neurofeedback versus other treatments for ADHD symptoms.

Table 3. Trials Included in Systematic Reviews of Neurofeedback versus Other Treatments for ADHD

Trials	Systematic Reviews				
	Cortese et al (2016) ⁹	Van Doren (2019) ⁵	Yan et al (2019) ⁶	Lambeiz et al (2020) ⁴	Riesco-Matias (2021) ¹⁰
Linden et al (1996)	●				
Li et al (2001)		●			
Heinrich et al (2004)	●	●		●	
Klingberg et al (2005)				●	
Bauregard et al (2006)	●			●	●
Zhang et al (2006)			●		
Chen et al (2007)			●		
Drechsler et al (2007)				●	
Kong et al (2007)			●		
Chen et al (2009)			●		
Gevensleben et al (2009)	●				●
Holtmann et al (2009)	●				
Ji et al (2009)			●		
Zuo et al (2009)			●		
Gevensleben et al (2010)		●			
Virta et al (2010)				●	

Trials	Systematic Reviews					
Bakhshayesh et al (2011)	●			●		●
Chen et al (2011)			●			
Prins et al (2011)				●		
Steiner et al (2011)	●			●		
Chang et al (2012)				●		
Fan et al (2012)			●			
Zhou et al (2012)			●			
Arnold et al (2013)	●	●				
Li et al (2013)			●			●
Meisel et al (2013)		●	●			
Miranda et al (2013)				●		
Ogrim et al (2013)						●
VanDongen et al (2013)	●					●
Chang et al (2014)				●		
Christiansen et al (2014)	●	●				
Du et al (2014)			●			
Maurizio et al (2014)	●					●
Meisel et al (2014)						●
Steiner et al (2014)	●	●				●
Vollebregt et al (2014)	●					
Bink et al (2015)	●	●				●
Choi et al (2015)				●		
Gapin et al (2015)						
Menezes et al (2015)				●		
Miranda et al (2015)						
Moreno et al (2015)			●			
Salomone et al (2015)				●		
Pan et al (2016)						
Yang et al (2016)			●			
Duric et al (2017)		●	●			●
Gelade et al (2017)		●	●	●		
Strehl et al (2017)						●
Tang et al (2017)			●			
Gelade et al (2018)						●
Minder et al (2018)						●
Sudnawa et al (2018)			●			●
Moreno-Garcia et al (2019)						●

ADHD: attention-deficit/hyperactivity disorder.

Table 4. Characteristics of Systematic Reviews and Meta-analyses of Neurofeedback for ADHD

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Cortese et al (2016) ⁹	To August 30, 2015	13	Children and adolescents with ADHD (any subtype) or hyperkinetic disorder	520 (14 to 94)	13 RCTs of neurofeedback vs. other care	Follow-up: 2 to 12 months
Van Doren et al (2019) ⁵	To November 29, 2017	10	Children and adolescents with a primary	256 (11 to 41)	10 RCTs of neurofeedback vs. other care	Follow-up: 2 to 12 months

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Yan et al (2019) ⁶	To August 22, 2018	18	Children, adolescents, and adults with ADHD	1535 (13 to 90)	18 RCTs of neurofeedback vs. methylphenidate	Follow-up: 1 to 6 months
Lambez et al (2020) ⁴	To December 2017	18	Children, adolescents, and adults with ADHD	618 (20 to 76)	18 RCTs of neurofeedback vs. biofeedback, cognitive behavioral therapy, cognitive training, or physical activity	Follow-up: 25 days to 8 months
Riesco-Matias et al (2021) ¹⁰	To July 18, 2018	17	Children and adolescents with a primary diagnosis of ADHD	NR	16 RCTs of neurofeedback vs. active and nonactive controls	Follow up: NR

ADHD: attention-deficit/hyperactivity disorder; NR: not reported; RCT: randomized controlled trial.

Table 5. Results of Systematic Reviews and Meta-analyses of Neurofeedback for ADHD

Study	ADHD Total Symptoms	ADHD Inattention Symptoms	ADHD Hyperactivity/Impulsiveness Symptoms	Inhibition
Cortese et al (2016)⁹				
Total N	13 trials (n=NR)	11 trials (n=NR)	10 trials (n=NR)	NR
Pooled Effect (95% CI)	Parent-reported: SMD, 0.35 (0.11 to 0.59)	Parent-reported: SMD, 0.36 (0.09 to 0.63)	Parent-reported: SMD, 0.26 (0.08 to 0.43)	NR
	Teacher-reported: SMD, 0.15 (-0.08 to 0.38)	Teacher-reported: SMD, 0.06 (-0.24 to 0.36)	Teacher-reported: SMD, 0.17 (-0.05 to 0.39)	
<i>P</i> (p)	41% (.06)	43% (.07)	0% (.8)	NR
Van Doren et al (2019)⁵				
Total N	NR	11 trials (n=NR)	11 trials (n=NR)	NR
Pooled Effect (95% CI)	NR	SMD, 0.31 (-0.01 to 0.63)	0.32 (0.15 to 0.49)	NR
<i>P</i> (p)	NR	70% (.06)	0% (.0003)	NR
Yan et al (2019)⁶				
Total N	4 trials (n=228)	4 trials (n=228)	4 trials (n=228)	NR
Pooled Effect (95% CI)	SMD, -0.578 (-1.063 to -0.092)	SMD, -0.667 (-1.245 to -0.109)	SMD, -0.474 (-0.860 to 0.088)	NR
<i>P</i> (p)	59% (.062)	70% (.019)	38% (.156)	NR
Lambez et al (2020)⁴				
Total N	NR	NR	NR	6 trials (n=203)
Pooled Effect (95% CI)	NR	NR	NR	SMD, 0.61 (-3.77 to 4.82)
<i>P</i> (p)	NR	NR	NR	0% (<.05)
Riesco-Matias et al (2021)¹⁰				
Total N	NR	Unblinded evaluation: 11 trials (n=674)	Unblinded evaluation: 11 trials (n=674)	NR
		Blinded	Blinded evaluation: 9 trials (n=573)	

Study	ADHD Total Symptoms	ADHD Inattention Symptoms	ADHD Hyperactivity/Impulsiveness Symptoms	Inhibition
		evaluation: 9 trials (n=573)		
Pooled Effect (95% CI)	NR	Unblinded evaluation: SMD, -0.33 (-0.56 to -0.10) Blinded evaluation: SMD, -0.25 (-0.45 to -0.04)	Unblinded evaluation: SMD, -0.17 (-0.33 to -0.02) Blinded evaluation: SMD, -0.16 (-0.32 to 0.01)	NR
I² (p)	NR	Unblinded: 49% (.005) Blinded: 30% (.02)	Unblinded: 0% (.03) Blinded: 0% (.06)	NR

ADHD: attention-deficit/hyperactivity disorder; CI: confidence interval; NR: not reported; SMD: standardized mean difference.

Randomized Controlled Trials Not Included in the Meta-Analyses

Several RCTs not included in the above systematic reviews are described below (Tables 6 to 9).^{11,7,12,13} Hasslinger et al (2022) published a multi-arm, pragmatic, RCT [NCT01841151] in 202 children and adolescents with ADHD (see Table 6 for trial characteristics) that evaluated the efficacy of 2 neurofeedback treatments (slow cortical potential [SCP] and Live Z-score) compared to working-memory training (active comparator) and treatment as usual (passive comparator).¹² The prespecified primary outcome measure¹⁴, was the self-, teacher- and parent-reported assessment of ADHD symptoms post-treatment and at 6 months using the Conners 3rd Edition scale. As only the inattention and hyperactivity/impulsivity Conners subscales were reported by Hasslinger et al, its results are not reported in Table 7. Neither neurofeedback treatment was superior to working-memory training for these outcome measures. Significant differences between SCP and treatment as usual were observed post-treatment for teacher- and parent-rated inattention, with no difference for other outcome measures at either timepoint. A statistically significant difference in Live Z-score over treatment as usual was only observed at the 6-month endpoint for teacher-rated inattention and hyperactivity/impulsivity. No other differences between Live Z-score and treatment as usual were observed. Secondary outcomes in this study included measures of teacher- and parent-rated executive function and self-assessed health-related quality of life using the Behavior Rating of Executive Functions (BRIEF) and KIDSCREEN-27 scales, respectively. There were no consistent differences between neurofeedback interventions and control interventions for these outcomes except for teacher-assessed executive function at 6 months follow-up, which found both neurofeedback interventions superior to working-memory training and treatment as usual. Limitations of this RCT are presented in Tables 8 and 9.

Table 6. Characteristics of RCTs of Neurofeedback in ADHD

Study	Countries	Sites	Dates	Participants	Interventions
Lim et al (2019) ¹¹	Singapore	1	January 2012 to June 2016	Children age 6 to 12 years diagnosed with ADHD	BCI-based neurofeedback attention training vs. untreated waitlist control for 8 weeks followed by BCI-based neurofeedback attention training for 20 weeks

Study	Countries	Sites	Dates	Participants	Interventions
Aggensteiner et al (2019) ⁷	Germany	NR (multicenter)	September 2009 to January 2013	Children age 7 to 9 years diagnosed with ADHD	SCP-based neurofeedback vs. EMG-based biofeedback
Arnold et al (2020) ¹⁵	US	2	NR	Children age 7 to 10 years diagnosed with moderate/severe ADHD and theta/beta ratio ≥ 4.5	Treatment consisted of downtraining theta power and uptraining beta power for 38 active neurofeedback treatments vs. 38 control treatments
Hasslinger et al (2022) ¹²	Sweden	1	2013 to 2019	Children age 9 to 17 years diagnosed with ADHD	4 arms: SCP neurofeedback, Live Z-score neurofeedback; working-memory training, and treatment as usual
Purper-Ouakil et al (2022) ¹³	France, Spain, Germany, Belgium, Switzerland	9	August 2016 to September 2017	Children age 7 to 13 years diagnosed with ADHD	At-home personalized neurofeedback training vs. methylphenidate

ADHD: attention-deficit/hyperactivity disorder; BCI: brain-computer interface; EMG: electromyography; NR: not reported; RCT: randomized controlled trial; SCP: slow cortical potential; US: United States.

Table 7. Results of RCTs of Neurofeedback in ADHD

Study	ADHD-RS	FBB-HKS	Conners 3-P
Lim et al (2019) ¹¹			
N	172		
BCI-based neurofeedback	8 weeks of intervention: 3.5 ± 3.87 20 weeks of intervention: 3.3 ± 5.55 4 weeks post-intervention: 4.7 ± 5.94		
Waitlist control	8 weeks of intervention: 1.9 ± 4.42 20 weeks of intervention: 1.4 ± 3.94 4 weeks post-intervention: 2.0 ± 4.26		
Difference [Neurofeedback - Control] (95% CI)	8 weeks of intervention: 1.6 points (0.3 to 0.29) 20 weeks of intervention: 2.4 points (1.6 to 3.2) 4 weeks post-intervention: 3.3 points (2.5 to 4.2)		
Aggensteiner et al (2019) ⁷			
N	144	144	
SCP-based neurofeedback	1.28	1.33	
EMG-based biofeedback	1.30	1.38	
Difference [Neurofeedback - Control] (95% CI)	NR	-0.04 (-0.27 to 0.14)	

Study	ADHD-RS	FBB-HKS	Conners 3-P
Arnold et al (2020)¹⁵			
N			144
Neurofeedback			Change from baseline to end of treatment: -0.561
			Change from baseline to 13-month follow-up: -0.612
Control (sham neurofeedback)			Change from baseline to end of treatment: -0.557
			Change from baseline to 13-month follow-up: -0.524
Between-group difference for change from baseline to end of treatment (95% CI)			0.004 (-0.19 to 0.20)
Between-group difference for change from baseline to 13-month follow-up (95% CI)			0.087 (-0.32 to 0.79)
Purper-Ouakil et al (2022)¹³			
N	149 (per protocol)		
Neurofeedback (day 90 - day 0)	-9.21		
Methylphenidate (day 90 - day 0)	-17.3		
Mean between-group difference at day 90 (90% CI)	8.09 (5.62 to 10.56)		
Noninferiority	Noninferiority of neurofeedback to methylphenidate not demonstrated		

ADHD-RS: attention deficit-hyperactivity disorder-rating scale; BCI: brain-computer interface; CI: confidence interval; Conners 3-P: Conners 3rd Edition-Parent; EMG: electromyography; FBB-HKS: Fremdbeurteilungsbogen für Hyperkinetische Störungen; NR: not reported; RCT: randomized controlled trial; SCP: slow cortical potential.

Table 8. Study Relevance Limitations of RCTs of Neurofeedback in ADHD

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Lim et al (2019) ¹¹	4. Included patients from a single site in Singapore				1. Follow-up occurred only 4 weeks after intervention
Aggensteiner et al (2019) ⁷	4. Included patients from Germany				
Arnold et al (2020) ¹⁵					
Hasslinger et al (2022) ¹²	4. Included patients from a single site in Sweden		1. Treatment as usual was not specifically defined	2. Focused on symptom measures as outcomes, which may not correlate with functioning	
Purper-Ouakil et al (2022) ¹³			2. Absence of sham neurofeedback or another nonactive group 1. Methylphenidate "optimally titrated" but		1. Absence of follow-up

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
			doses not specifically defined		

ADHD: attention-deficit/hyperactivity disorder; RCT: randomized controlled trial.

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aPopulation key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^bIntervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^cComparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^dOutcomes 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.

^eFollow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations of RCTs of Neurofeedback in ADHD

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Lim et al (2019) ¹¹	3.	1. Patients, parents, and investigators were unblinded; outcome assessors and teachers were blinded				
Aggensteiner et al (2019) ⁷	3.	1. Patients were unblinded; blinding of parents and teachers not reported			1.	
Arnold et al (2020) ¹⁵						
Hasslinger et al (2022) ¹²		1. Parents were unblinded		1. Missing data, especially for teacher ratings		
Purper-Ouakil et al (2022) ¹³		1. Parents and clinicians were unblinded			1. Sample size calculation were done but power not specifically stated	1. Secondary analyses exploratory only

ADHD: attention-deficit/hyperactivity disorder; RCT: randomized controlled trial.

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aAllocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^bBlinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^cSelective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^dData 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).

^ePower key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^fStatistical 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: Attention Deficit-Hyperactivity Disorder

Several meta-analyses and 5 additional moderately sized RCTs (N range, 144 to 202 patients) have compared neurofeedback with methylphenidate, biofeedback, cognitive behavioral therapy, cognitive training, or physical activity. These studies found either small to moderate or no benefit of neurofeedback, and sustained long-term benefit (e.g., at 6 to 13 months) has not been consistently demonstrated. Studies using active controls have suggested that at least part of the effect of neurofeedback might be due to attention skills training, biofeedback, relaxation training, and/or other nonspecific effects. Two of the RCTs indicated that any beneficial effects were more likely to be reported by evaluators unblinded to treatment (parents), than by evaluators blinded (teachers) to treatment, which would suggest bias in the nonblinded evaluations. Moreover, a meta-analysis found no effect of neurofeedback on objective measures of attention and inhibition. Additional research with blinded evaluation of outcomes is needed to demonstrate the effect of neurofeedback on ADHD.

Disorders Other Than Attention Deficit-Hyperactivity Disorder

Clinical Context and Therapy Purpose

The purpose of neurofeedback is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as behavioral therapy and pharmacologic therapy, in individuals with disorders other than ADHD.

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

Populations

The relevant population of interest is individuals with disorders other than ADHD, including psychiatric, central nervous system, or pain disorders.

Interventions

The therapy being considered is neurofeedback.

Comparators

Comparators of interest include behavioral therapy and pharmacologic therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life (Tables 10 and 11).

Table 10. Outcomes of Interest for Individuals with Disorders Other than ADHD

Outcomes	Details
Reduction of symptoms as observed by parents and patients	Attention Switching Task; Impact of Pediatric Epilepsy Scale; PTSD symptoms [Timing: 6 weeks]

ADHD: attention-deficit/hyperactivity disorder; PTSD: post-traumatic stress disorder.

Table 11. Health Outcome Measures Relevant to Disorders other than ADHD

Outcome	Measure (units)	Description	Clinically Meaningful Difference (If Known)
Attention Switching Task	msec	Computerized task measuring ability to adjust behavior in accordance with changing task goals	Not defined ¹⁶ .
Impact of Pediatric Epilepsy Scale	Scale from 0 to 33	Questionnaire administered to parent or	Not defined ¹⁶ .

Outcome	Measure (units)	Description	Clinically Meaningful Difference (If Known)
	Higher scores indicate more symptoms	guardian measuring domains of academic improvement, social adaptation, and self-esteem	
PTSD symptoms	Various questionnaires	Various questionnaires administered to patients measuring the frequency and intensity of PTSD symptoms	Not defined ¹⁷ .
	Higher scores indicate more symptoms		
Sleep efficiency	Percentage	Measure of percentage of total time in bed spent asleep	Not defined ¹⁸ .
	Lower values indicate more symptoms		
Sleep fragmentation	Occurrences	Measure of the number of awakening episodes by polysomnography or patient diary	Not defined ¹⁸ .
	Higher values indicate more symptoms		
Total sleep time	Minutes	Measure of time spent asleep among total recording time	Not defined ¹⁸ .
	Lower values indicate more symptoms		

ADHD: attention-deficit/hyperactivity disorder; PTSD: post-traumatic stress disorder.

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;
- Within each category of study design, studies with larger sample size and longer duration were preferred;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Chronic Insomnia

Systematic Review with Meta-Analysis

A systematic review by Melo et al (2019) included 7 RCTs of biofeedback techniques, including neurofeedback, in the treatment of chronic insomnia.¹⁹ The authors identified conflicting results in comparisons of neurofeedback with other cognitive behavioral therapy techniques, placebo, and no treatment. A majority of outcomes demonstrated no significant differences between comparison groups. A majority of studies had a high risk of bias related to blinding of participants and personnel and incomplete outcome data. Characteristics and results from the meta-analysis are summarized in Tables 12 and 13, respectively.

Table 12. Characteristics of a Systematic Review and Meta-analysis of Neurofeedback for Chronic Insomnia

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Melo et al (2019) ¹⁹ .	To 2019	7	Adults with chronic insomnia	224 (18 to 48)	7 RCTs of biofeedback techniques	10 days to 36 months

RCT: randomized controlled trial.

Table 13. Results of a Systematic Review and Meta-analysis of Neurofeedback for Chronic Insomnia

Study	Total Sleep Time	Sleep Fragmentation	Sleep Efficiency
Melo et al (2019) ¹⁹			
Total N	2 trials (n=NR)	2 trials (n=NR)	2 trials (n=NR)
Pooled Effect (95% CI)	No significant difference between biofeedback and placebo (effect estimate NR)	Mean difference in number of awakenings, -4.5 (-8.33 to -0.67)	No significant difference between biofeedback and placebo as measured by either polysomnography or sleep diaries (effect estimates NR)
P (p)	NR	NR	NR

CI: confidence interval; NR: not reported.

Epilepsy

Randomized Controlled Trials

An RCT by Morales-Quezada et al (2019) randomized children with focal epilepsy to sensorimotor rhythm neurofeedback, SCP neurofeedback, or sham neurofeedback for 25 sessions over 5 weeks.¹⁶ At the end of the intervention period, only the sensorimotor rhythm neurofeedback group demonstrated significant improvement in the activity switching task and all groups demonstrated significant improvements in quality of life. Characteristics and results from the RCT are summarized in Tables 14 and 15, respectively. Tables 16 and 17 summarize relevant limitations.

Table 14. Characteristics of a Recent RCT of Neurofeedback in Epilepsy

Study	Countries	Sites	Dates	Participants	Interventions
Morales-Quezada et al (2019) ¹⁶	Mexico	1	NR	Children and adolescents with focal epilepsy responsive to antiepileptic pharmacotherapy and cognitive difficulties in school	SMR neurofeedback, SCP neurofeedback, or sham neurofeedback over 5 weeks

NR: not reported; RCT: randomized controlled trial; SCP: slow cortical potential, SMR: sensorimotor rhythm.

Table 15. Results of a RCT of Neurofeedback in Epilepsy

Study	Attention Switching Task	Impact of Pediatric Epilepsy Scale
Morales-Quezada et al (2019) ¹⁶		
N	44	44
SMR neurofeedback	Significant improvement from baseline to postintervention (-757 msec; p=.015) and follow-up (-644; p=.04)	1.5-point change from baseline (p=.002)
SCP neurofeedback	Not significant (effect estimate, NR)	1.9-point change from baseline (p=.001)
Sham neurofeedback	Not significant (effect estimate, NR)	1.3-point change from baseline (p=.006)
Difference [Neurofeedback - Control] (95% CI)	NR	NR

CI: confidence interval; NR: not reported; RCT: randomized controlled trial; SCP: slow cortical potential; SMR: sensorimotor rhythm.

Table 16. Study Relevance Limitations of a RCT of Neurofeedback in Epilepsy

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Morales-Quezada et al (2019) ¹⁶	4. Included patients from a				

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
	single site in Mexico				

RCT: randomized controlled trial.

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aPopulation key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^bIntervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^cComparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^dOutcomes 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.

^eFollow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 17. Study Design and Conduct Limitations of a RCT of Neurofeedback

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Morales-Quezada et al (2019) ¹⁶	3.				1.	

RCT: randomized controlled trial.

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aAllocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^bBlinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^cSelective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^dData 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).

^ePower key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^fStatistical 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.

Substance Abuse

Systematic Reviews with Meta-Analyses

A systematic review by Sokhadze et al (2008) of neurofeedback as a treatment for substance abuse disorders described difficulties in assessing the efficacy of neurofeedback and other substance abuse treatments.²⁰ Study shortcomings included a lack of clearly established outcome measures, differing effects of the various drugs, the presence of comorbid conditions, the absence of a criterion standard treatment, and use as an add-on to other behavioral treatment regimens. Reviewers concluded that alpha-theta training, when combined with an inpatient rehabilitation program for alcohol dependency or stimulant abuse, would be classified as level 3 or "probably efficacious." This level is based on beneficial effects shown in multiple observational studies, clinical studies, wait-list control studies, or within-subject or between-subject replication studies. Reviewers also noted that few large-scale studies of neurofeedback in addictive disorders have been reported and that the evidence for alpha-theta training has not been shown to be superior to sham treatment.

Randomized Controlled Trials

An RCT by Gabrielsen et al (2022) randomized adults with substance abuse disorders enrolled in outpatient abuse programs to either 20 sessions (30 minutes each) of infralow (ILF) neurofeedback plus standard of care, or standard of care alone, over a mean of 5 months.²¹ At the end of the intervention period, both groups demonstrated a significant improvement in quality of life scores from baseline, but there was no difference between groups. Restlessness was reportedly significantly lower in the ILF-neurofeedback group compared to standard of care post-treatment, but this was a secondary endpoint, meaning the study was not powered to find differences only in this endpoint. Individuals were not stratified based on drugs of abuse and there was a lack of sham neurofeedback, limiting results. Characteristics and results from the RCT are summarized in Tables 18 and 19, respectively. Tables 20 and 21 summarize relevant limitations.

Table 18. Characteristics of a Recent RCT of Neurofeedback in Substance Abuse Disorders

Study	Countries Sites	Dates	Participants	Interventions
Gabrielsen et al (2022) ²¹	Norway 1	September 2017 to March 2020	Adults enrolled in outpatient substance abuse program within the past month and not on opioid maintenance (65% male).	20 sessions (30 mins each) of ILF-neurofeedback plus standard care or standard care alone.

ILF: infralow; RCT: randomized controlled trial.

Table 19. Results of a RCT of Neurofeedback in Substance Abuse Disorders

Study	QoL post-treatment ^a	Restlessness ^b
Gabrielsen et al (2022) ²¹		
N	93	93
ILF neurofeedback + standard care	0.54±0.17	4.1±2.5
Standard care alone	0.58±0.16	5.9±2.8
Mean difference (95% CI); p-value	-0.04 (-0.13 to 0.04); p=.28	-1.8 (-3.1 to -0.5); p=.006

^aMeasured using the QoL-5 scale, ranging from 0.1 to 0.9, where 0.9 is the highest (best) score

^bMeasured using 10 cm visual analog scales

CI: confidence interval; ILF: infralow; QoL: quality of life; RCT: randomized controlled trial.

Table 20. Study Relevance Limitations of a RCT of Neurofeedback in Substance Abuse Disorders

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Gabrielsen et al (2022) ²¹	4. Included patients from a single site in Norway; 5. broad inclusion criteria		2. No sham neurofeedback control		

RCT: randomized controlled trial.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 21. Study Design and Conduct Limitations of a RCT of Neurofeedback in Substance Abuse Disorders

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Gabrielsen et al (2022) ²¹		1. No sham control to allow for participant blinding.			4. Study likely underpowered based on power calculation	

RCT: randomized controlled trial.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^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); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^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; 5. Other.

Pediatric Brain Tumor Survivors

De Ruiter et al (2016) reported on a multicenter, triple-blind RCT of neurofeedback in 80 pediatric brain tumor survivors who had cognitive impairments.²² The specific neurofeedback module was based on individual EEG, and participants, parents, trainers, and researchers handling the data were blinded to assignment to the active or sham neurofeedback module. At the end of training and 6-month follow-up, there were no significant differences between the neurofeedback and sham feedback groups on the primary outcome measures for cognitive performance, which included attention, processing speed, memory, executive functioning, visuomotor integration, and intelligence.

Post-Traumatic Stress Disorder Systematic Reviews with Meta-Analyses

A meta-analysis by Steingrimsson et al (2020) evaluated 4 RCTs of adults with post-traumatic stress disorder (PTSD) treated with neurofeedback.¹⁷ Compared with sham neurofeedback, no treatment or other treatment, neurofeedback was associated with significant improvement in PTSD symptoms. Other primary outcomes were only reported in 1 trial each, and the authors concluded there was uncertainty regarding the ability of neurofeedback to improve PTSD symptoms, self-rated suicidality, executive cognitive functioning, and medication use. All studies were at moderate to high risk for bias, and were assessed as having some indirectness and imprecision.

Hong and Park (2022) conducted a meta-analysis of 7 RCTs of adults with PTSD treated with neurofeedback.²³ Three studies used functional magnetic resonance imaging (fMRI) based neurofeedback and 4 studies used EEG-based neurofeedback. The overall effect of all studies pooled together demonstrated a significant improvement in PTSD symptoms with neurofeedback compared to sham neurofeedback, no treatment, or other treatment. When analyzed by type of neurofeedback, the significant improvement in PTSD symptoms remained with EEG-based neurofeedback, but not with fMRI. Five studies overall assessed anxiety and depression with various validated scales. Overall, there was no significant impact on anxiety and depression with neurofeedback compared to control group. Two studies demonstrated a high risk of performance or detection bias, while all other studies

demonstrated overall low risk of bias. Characteristics and results of the meta-analyses are summarized in Tables 22 through 24.

Table 22. Comparison of Studies Included in Systematic Review and Meta-analyses of Neurofeedback for PTSD

Study	Steingrimsson et al (2020) ¹⁷ ,	Hong and Park (2022) ²³ ,
Peniston et al (1991)	●	
Kelson et al (2013)	●	
van der Kolk et al (2016)	●	●
Noohi et al (2017)	●	●
Misaki et al (2018)		●
Zotsev et al (2018)		●
Du Bois et al (2021)		●
Leem et al (2021)		●
Misaki et al (2021)		●

PTSD: post-traumatic stress disorder.

Table 23. Characteristics of Systematic Reviews and Meta-analyses of Neurofeedback for PTSD

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Steingrimsson et al (2020) ¹⁷ ,	To 2019	4	Adults with PTSD	123 (12 to 52)	4 RCTs of EEG-based neurofeedback for PTSD vs. sham neurofeedback, other treatment, or no treatment	Follow-up: 4 weeks to 30 months
Hong and Park (2022) ²³ ,	To 2021	7	Adults with PTSD	194 (19 to 52)	3 RCTs of fMRI-based neurofeedback and 4 RCTs of EEG-based neurofeedback for PTSD vs. sham neurofeedback, other treatment, or no treatment	Range, 3 to 25 sessions between 6 and 40 mins each

EEG: electroencephalography; fMRI: functional magnetic resonance imaging; PTSD: post-traumatic stress disorder; RCT: randomized controlled trial.

Table 24. Results of Systematic Reviews and Meta-analyses of Neurofeedback for PTSD

Study	Self-Harm	PTSD Symptoms
Steingrimsson et al (2020) ¹⁷ ,		
Total N	1 trial (n=NR)	4 trials (n=123)
Pooled Effect (95% CI)	1.4-point improvement with neurofeedback (p=.002)	SMD, 2.3 (-4.37 to -0.24)
<i>I</i> ² (p)	89% (<.0001)	NR

Study	Self-Harm	PTSD Symptoms
Hong and Park (2022)²³		
Overall effect		
Anxiety and Depression		
Total N	5 trials (n=123)	7 trials (n=194)
Pooled Effect (95% CI)	difference, -0.562 (-1.230 to 0.106)	difference, -0.789 (-1.004 to -0.395)
P (p)	68.221% (.013)	67.188% (.006)
fMRI-based neurofeedback only		
Total N	NR	3 trials (n=74)
Pooled Effect (95% CI)		difference, -0.368 (-0.851 to 0.115)
P (p)		0.0 (.925)
EEG-based neurofeedback trials only		
Total N		4 trials (n=120)
Pooled Effect (95% CI)		difference, -1.132 (-2.061 to -0.203)
P (p)		NR

CI: confidence interval; EEG: electroencephalography; fMRI: functional magnetic resonance imaging; NR: not reported; PTSD: post-traumatic stress disorder; SMD: standardized mean difference.

Other Disorders

Literature searches and a systematic review by Schoenberg et al (2014) assessing biofeedback for psychiatric and neurologic disorders²⁴ have identified small studies (case reports, case series, comparative cohorts, small RCTs) of neurofeedback for the following conditions:

- Anxiety²⁴,
- Asperger syndrome²⁴,
- Autism spectrum disorder^{25,26},
- Cigarette cravings^{27,28},
- Chronic pain²⁹,
- Cognitive impairment³⁰,
- Depression^{31,32,33},
- Depression, pain, or fatigue in patients with multiple sclerosis³⁴,
- Depression in alcohol addiction²⁴,
- Dissociative identity disorder²⁴,
- Fall risk³⁵,
- Fibromyalgia^{36,37},
- Insomnia³⁸,
- Headache^{39,40},
- Lower back pain⁴¹,
- Multiple sclerosis⁴²,
- Overweight and obesity^{43,44},
- Obsessive-compulsive disorder^{45,46},
- Parkinson disease^{47,48,49},
- Schizophrenia^{50,51,24,52},
- Stroke^{53,54},
- Tinnitus⁵⁵,
- Tourette syndrome^{56,57},

Section Summary: Disorders Other Than Attention Deficit-Hyperactivity Disorder

The evidence for neurofeedback in individuals with disorders other than ADHD includes case reports, case series, comparative cohorts, small RCTs, and systematic reviews of these studies. For these disorders, the evidence is poor, and a number of questions regarding clinical efficacy remain unanswered. Larger RCTs that include either a sham or active control are needed to evaluate the effect of neurofeedback for these conditions.

Supplemental Information

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

Practice Guidelines and Position Statements

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

American Academy of Pediatrics

In 2019, the American Academy of Pediatrics (AAP) published a guideline update to the 2011 guideline for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents.⁵⁸ The guideline states that electroencephalogram (EEG) biofeedback is one of several nonmedication treatments that have either too little evidence to support their recommendation for use or have little or no benefit.

The AAP Section on Integrative Medicine (2016), in a clinical report on mind-body therapies in children and youth, stated that research suggests benefits of peripheral forms of biofeedback, including EEG biofeedback (neurofeedback) in ADHD.⁵⁹ The report noted no significant contraindications to the use of biofeedback, with the only barriers potentially being financial in nature. Of note, this clinical report has expired and is under review by the authorship team.

National Institute for Health and Care Excellence

In 2013, NICE issued guidance on management and support of children on the autism spectrum.⁶⁰ The Institute stated that a number of treatments were considered but are not recommended, including neurofeedback.

Society for Developmental and Behavioral Pediatrics

The Society for Development and Behavioral Pediatrics (SDBP) published a guideline in 2020 on the assessment and treatment of children and adolescents with complex ADHD.⁶¹ Regarding neurofeedback, the guidelines state: "Additional nonpharmacological ADHD interventions have been developed such as cognitive training (e.g., working memory training) and neurofeedback. Although these approaches have shown some improvement in laboratory-based, task-specific outcomes, none have demonstrated sufficient evidence of effectiveness in real-world domains of functioning (e.g., behavior at home and school, academic performance, peer relationships) to recommend them for use in practice with children and adolescents with ADHD."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services published a national coverage determination on biofeedback therapy.⁶² The Centers for Medicare & Medicaid Services stated that "biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions". The effective date of this version of the national coverage determination has not been posted.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 25. The completion date for various registered trials of neurofeedback have passed without publication of results, suggesting the potential for publication bias.

Table 25. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04408521	Effect of Long-lasting EEG-Neurofeedback on Attention Control and Impulsivity in Adult Attention-Deficit/Hyperactivity Disorder (ADHD)	48	April 2023
NCT04469335	Comparative Clinical Trial With Double-blind Randomized Sham Control and Additive Treatment Toward Efficacy of Mobile Neurofeedback for ADHD Youth : An Exploratory Study.	165	Dec 2021
<i>Unpublished</i>			
NCT04097522	Neurofeedback for Chronic Pain Project (NFB Project)	102	Oct 2020
NCT01841151	Does Neurofeedback and Working Memory Training Improve Core Symptoms of ADHD in Children and Adolescents? A Comparative, Randomized and Controlled Study	202	Oct 2020
NCT04220112	Comparing Real-time fMRI Neurofeedback Versus Sham for Altering Limbic and Eating Disturbances in Anorexia Nervosa	33	Sep 2022

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

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

Type	Code	Description
CPT®	90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
	90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
	90901	Biofeedback training by any modality
HCPCS	None	

Policy History

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

Effective Date	Action
09/30/2014	BCBSA Medical Policy adoption
04/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
08/01/2018	Policy revision without position change
09/01/2019	Policy revision without position change
09/01/2023	Policy reactivated. Previously archived from 07/01/2020 to 08/31/2023.

Definitions of Decision Determinations

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

therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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

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

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

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

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

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

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

Appendix A

POLICY STATEMENT	
BEFORE	AFTER <i>Blue font: Verbiage Changes/Additions</i>
Reactivated Policy Policy Statement: N/A	Neurofeedback 2.01.28 Policy Statement: <i>I. Neurofeedback is considered investigational.</i>