Medical Policy

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***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: Neurofeedback (i.e. EEG Biofeedback)

Description/Background

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

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 CNS functioning can help train patients to modify or control their abnormal brain activity. Upregulating or downregulating neural activity with real-time feedback of fMRI signals is also being explored.

Two EEG training protocols, training of SCPs and theta/beta training, are typically used in children with attention deficit/hyperactivity disorder (ADHD). For training of SCPs, surface-negative SCPs 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 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 the treatment of migraine headaches.

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 FDA approval. FDA product codes: HCC, GWQ.

Medical Policy Statement

Neurofeedback is experimental/investigational. The evidence is insufficient to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

90875 90876 90901

Rationale

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 ADHD.

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

Populations
The relevant population of interest are 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 1 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 54Higher scores indicate moresymptoms18 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
Conners Parent Rating Scale for ADHD	Scale from 0 to 144Higher 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
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 Higher scores indicate more symptoms	Items can be rated by parents or teacher	Not defined

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.(4-6). 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.
- 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).(4-6,9,10) 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,]	Lambez 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)				●	
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 diagnosis of ADHD	256 (11 to 41)	10 RCTs of neurofeedback vs. other care	Follow-up: 2 to 12 months
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) Teacher-reported: SMD, 0.15 (-0.08 to 0.38)	Parent-reported: SMD, 0.36 (0.09 to 0.63) Teacher-reported: SMD, 0.06 (-0.24 to 0.36)	Parent-reported: SMD, 0.26 (0.08 to 0.43) Teacher-reported: SMD, 0.17 (-0.05 to 0.39)	NR
I^2 (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^2 (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^2 (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^2 (p)	NR	NR	NR	0% (<.05)
Riesco-Matias et al (2021)[10,]				
Total N	NR	Unblinded evaluation: 11 trials (n=674) Blinded evaluation: 9 trials (n=573)	Unblinded evaluation:11 trials (n=674) Blinded evaluation: 9 trials (n=573)	NR
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
I^2 (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).(11-13) 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 measure (14) 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
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 down training 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)	
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 doses not specifically defined		1. Absence of follow-up

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.
[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 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 done but power not specifically stated	1. Secondary analyses were 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.
[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: 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 ADHD

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 PICOs were 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 Attention-Deficit/Hyperactivity Disorder

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 Longer duration indicates more symptoms	Computerized task measuring ability to adjust behavior in accordance with changing task goals	Not defined
Impact of Pediatric Epilepsy Scale	Scale from 0 to 33 Higher scores indicate more symptoms	Questionnaire administered to parent or guardian measuring domains of academic improvement, social adaptation, and self-esteem	Not defined
PTSD symptoms	Various questionnaires Higher scores indicate more symptoms	Various questionnaires administered to patients measuring frequency and intensity of PTSD symptoms	Not defined
Sleep efficiency	Percentage Lower values indicate more symptoms	Measure of percentage of total time in bed spent asleep	Not defined
Sleep fragmentation	Occurrences Higher values indicate more symptoms	Measure of number of awakening episodes by polysomnography or patient diary	Not defined
Total sleep time	Minutes Lower values indicate more symptoms	Measure of time spent asleep among total recording time	Not defined

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.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Chronic Insomnia

Systematic Review with Meta-Analysis

A systematic review by Melo (2019) reviewed 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 were at 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)	To 2019	7	Adults with chronic insomnia	224 (18-48)	7 RCTs of biofeedback techniques	10 days to 36 months

RCT: randomized controlled trial

Table 13. Results of Systematic Reviews and Meta-analyses of Neurofeedback for Chronic Insomnia

Study	Total Sleep Time	Sleep Fragmentation	Sleep Efficiency
Melo et al (2019)			
Total (N)	2 Trials (n=NR)	2 Trials (n=NR)	2 Trials (n=NR)
Pooled Effect (95% CL)	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)
I^2 (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, slow cortical potential (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)	Mexico	1	NR	Children and adolescents with focal epilepsy responsive to antiepileptic pharmacotherapy and cognitive difficulties in school	Sensorimotor rhythm neurofeedback, SCP neurofeedback, or sham neurofeedback over 5 weeks

NR: not reported; SCP: slow cortical potential; RCT: randomized control trial; 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)		
N	44	44
SMR neurofeedback	Significant improvement from baseline to postintervention (-757 msec; p=0.015) and follow-up (-644; p=0.04)	1.5 – point change from baseline (p=0,002)
SCP neurofeedback	Not significant (effect estimate, NR)	1.9-point change from baseline (p=0.001)
Sham neurofeedback	Not significant (effect estimate, NR)	1.3-point change from baseline (p=0.006)
Difference [Neurofeedback - Control] (95% CI)	NR	NR

CI: confidence interval; NR: not reported; RCT: randomized control 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)	4. Included patients from a single site in Mexico				

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

Table 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.
[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.

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, presence of comorbid conditions, 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 III 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)	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

[a]Measured using the QoL-5 scale, ranging from 0.1 to 0.9, where 0.9 is the highest (best) score
[b]Measured 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 a multicenter, triple-blinded 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 at 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, of 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)		●
Zotev 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)	To 2019	4	Adults with PTSD	123 (12-52)	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)	To 2021	7	Adults with PTSD	194 (19 to 52)	3 RCTs of fMRI-based neurofeedback and 4 RCTs of EEG-based neurofeedback	Range, 3 to 25 sessions between 6

	for PTSD vs. sham neurofeedback, other treatment, or no treatment	and 40 mins each

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

Table 24. Results of a Systematic Review and Meta-analysis 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^2 (p)	89% (<.0001)	NR
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)
I^2 (p)	68.221% (.013)	67.188% (.006)
fMRI-based neurofeedback only	NR	
Total N		3 trials (n=74)
Pooled Effect (95% CI)		difference, -0.368 (-0.851 to 0.115)
I^2 (p)		0.0 (.925)
EEG-based neurofeedback trials only	NR	
Total N		4 trials (n=120)
Pooled Effect (95% CI)		difference, -1.132 (-2.061 to -0.203)
I^2 (p)		NR

CI: confidence level; 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 neurologic disorders (24) have identified small studies (case reports, case series, comparative cohorts, small RCTs) of neurofeedback for the following conditions:

- Anxiety
- Asperger syndrome
- Autism spectrum disorder
- Cigarette cravings
- Chronic pain
- Depression
- Depression and fatigue in patients with multiple sclerosis
- Depression in alcohol addiction
- Dissociative identity disorder
- Fibromyalgia
- Insomnia
- Headache
- Childhood obesity
- Obsessive-compulsive disorder
- Parkinson disease
- Post-traumatic stress disorder (PTSD)
- Schizophrenia
- Stroke
- Tourette syndrome

Section Summary: Disorders Other Than ADHD

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.

SUMMARY OF EVIDENCE

For individuals who have ADHD who receive neurofeedback, the evidence includes RCTs and a meta-analyses. The relevant outcomes are symptoms, functional outcomes, and QOL. Several meta-analyses and at least 5 additional moderately sized RCTs (n range, 144 to 202 patients) have compared neurofeedback with methylphenidate, biofeedback, cognitive behavioral therapy, cognitive training, physical activity, or sham neurofeedback. Collectively, these studies found either small or no benefit of neurofeedback. A meta-analysis also found no effect of neurofeedback on objective measures of attention and inhibition. Studies that used active controls have suggested that at least part of the effect of neurofeedback may be due to attention skills training, relaxation training, and/or other nonspecific effects. Also, the beneficial effects of neurofeedback are more likely to be reported by evaluators unblinded to treatment (parents) than by evaluators blinded to treatment (teachers),suggesting bias in the nonblinded evaluations. Additional research with blinded evaluation of outcomes is needed to demonstrate the effect of neurofeedback on ADHD. However, the completion dates for some registered trials of neurofeedback in ADHD have passed without publication of results, suggesting the potential for publication bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have disorders other than ADHD (e.g., chronic insomnia, epilepsy, substance abuse, pediatric brain tumors and PTSD) who receive neurofeedback, the evidence includes case reports, case series, comparative cohorts, small RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. For these other disorders, including psychiatric, neurologic, and pain syndromes, the evidence is poor and several questions concerning 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. However, the completion dates for some registered trials of neurofeedback in disorders other than ADHD have passed without publication of results, suggesting the potential for publication bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Pediatrics

The American Academy of Pediatrics (2019) published a guideline update to the 2011 guideline for the treatment of ADHD in children and adolescents.(58) The guideline states that EEG biofeedback is one of several nonmedication treatments that have either too little evidence to support their recommendation 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 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

The National Institute for Health and Care Excellence (2013) issued guideline on management and support of children on the autism spectrum.(60) The Institute stated that the 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."

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
Ongoing			
NCT04408521	Effect of Long-lasting EEG-Neurofeedback on Attention Control and Impulsivity in Adult Attention-Deficit/Hyperactivity Disorder (ADHD)	48	Apr 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
Unpublished			
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	220	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.

Government Regulations

National/Local:

CMS does not have a national or local coverage determination specific to neurofeedback.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Biofeedback

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 10/25/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/13	10/16/12	11/8/12	Joint policy established
7/1/13	4/16/13	4/29/13	Policy position changed to "established" for children with ADHD
1/1/15	10/24/14	11/3/14	Routine maintenance
1/1/16	10/13/15	10/27/15	Routine maintenance Removed age and visit limits
1/1/17	10/11/16	10/11/16	• Routine maintenance • Continue to diverge from BCBSA policy • Clarification added to inclusions
1/1/18	11/10/17	10/31/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance (slp)
1/1/24	10/17/23		Routine maintenance (slp) Vendor managed: N/A
3/1/24	12/19/23		• Status changed to EI based on market and SME recommendation (slp) • Aligns with BCBSA • Vendor managed: N/A • (i.e. EEG Biofeedback) added to end of title

Next Review Date: 4th Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: NEUROFEEDBACK (I.E. EEG BIOFEEDBACK)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.