Policy Statement

Neurofeedback is considered investigational.

Policy Guidelines

Note: Some Blue Shield of California (BSC) plans exclude coverage of biofeedback. Please check benefit plan descriptions for details.

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

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 (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

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

This review was informed by a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (1997). Literature published since that 1997 TEC Assessment consists of studies that have evaluated neurofeedback for a variety of clinical indications, with the greatest amount of scientific literature published on the treatment of attention-deficit/hyperactivity disorder (ADHD).

**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 patients with ADHD.

The question addressed in this evidence review is: Does neurofeedback reduce symptoms and improve functional outcomes in patients with ADHD or other psychiatric, central nervous system, or pain disorders?

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

**Patients**
The relevant population of interest are individuals with ADHD.

**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.
Patients with ADHD are actively managed by psychologists, psychiatrists, and primary care providers in an outpatient clinical setting.

**Comparators**
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. Treatment is actively managed by psychologists, psychiatrists, and primary care providers in an outpatient clinical setting.

**Outcomes**
The general outcomes of interest are symptoms, functional outcomes, and QOL.

**Table 1. Outcomes of Interest for Individuals with Attention-Deficit/ Hyperactivity Disorder**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Details</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>Outcomes as reported by assessors (parents most-often, or teachers, usually unblinded and with high-risk of bias)</td>
<td>Greater than 1 year</td>
</tr>
</tbody>
</table>

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

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

**Systematic Reviews with Meta-Analysis**
Cortese et al (2016), on behalf of the European ADHD Guidelines Group, reported on a meta-analysis of 13 RCTs (total n=520 participants) evaluating neurofeedback for ADHD. When outcomes were reported by assessors who were the least likely to be blinded (parents), there were small-to-moderate effects for total symptoms, inattention, and hyperactivity/impulsivity (see Table 1). However, the effects were not significant when the likelihood of blinding was higher (teacher reported). There were no benefits on objective measures of attention and inhibition. The larger trials included in the meta-analysis are described in the next section.

**Table 2. Summary of Meta-Analytic Outcomes**

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>No. of Trials</th>
<th>Standardized Effect Size</th>
<th>95% Confidence Interval</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total symptoms</td>
<td>13</td>
<td>0.35</td>
<td>0.11 to 0.59</td>
<td>0.004</td>
</tr>
<tr>
<td>Inattention</td>
<td>11</td>
<td>0.36</td>
<td>0.09 to 0.63</td>
<td>0.009</td>
</tr>
<tr>
<td>Hyper/impulsivity</td>
<td>10</td>
<td>0.26</td>
<td>0.08 to 0.043</td>
<td>0.004</td>
</tr>
<tr>
<td>Teacher reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total symptoms</td>
<td>8</td>
<td>0.15</td>
<td>-0.08 to 0.38</td>
<td>NS</td>
</tr>
<tr>
<td>Inattention</td>
<td>7</td>
<td>0.06</td>
<td>-0.24 to 0.36</td>
<td>NS</td>
</tr>
<tr>
<td>Hyper/impulsivity</td>
<td>7</td>
<td>0.17</td>
<td>-0.05 to 0.39</td>
<td>NS</td>
</tr>
</tbody>
</table>

Adapted from Cortese et al (2016).² NS: not significant.

**Randomized Controlled Trials**
RCTs Included in the Meta-Analysis
To control for nonspecific effects (attention training) and confounding variables (parental engagement), Gevensleben et al (2009) compared neurofeedback with a control intervention using a computerized attention skills training.³ All children were drug-naive or drug-free without...
During training, both groups participated in 2 blocks of 9 sessions (100 min/session plus a break), with 2 to 3 sessions per week, and parents were informed that both treatments were expected to be beneficial but were not informed as to which training their child had been assigned. A total of 102 children were randomized in a 3:2 ratio; 8 children were excluded due to the need for medical treatment or noncompliance with the study protocol by either the children or their parents, with 59 enrolled in intervention group and 35 randomized to the control; the majority completed follow-up (92%). Slow cortical potentials and theta/beta training were compared by starting with one type of training in the first block and then the other (counterbalanced order) in the second block. Evaluations were performed by the teachers, who were not blinded to the treatment.

At the end of training/testing, there were no significant differences in parents' attitudes toward the two training conditions or in the perceived motivation of their children. Approximately 40% of the parents either did not know which training their child had participated in or had guessed incorrectly. Both parents and teachers rated the neurofeedback group as more improved on the hyperactivity subcomponent of a Strength and Disabilities Questionnaire (e.g., 19% vs 3% improved, respectively) and a German ADHD rating scale, the Fremdbeurteilungsbogen für Hyperkinetische Störungen (FBB-HKS; [e.g., 26% vs 9% improved, respectively]). Thirty (52%) children in the neurofeedback group and 10 (29%) children in the attention training group improved more than 25% on FBB-HKS scores (odds ratio, 2.68), which was the primary outcome measure. Scores on other components of the Strength and Disabilities Questionnaire-including emotional symptoms, conduct problems, peer problems, and prosocial behavior-did not differ between the two training conditions. No significant differences were noted between the two neurofeedback training protocols. Results of this RCT suggested that neurofeedback might have specific effects on attention and hyperactivity beyond those achieved by attention training and parental involvement. The authors noted that future studies should further address the specificity of effects and how to optimize the benefit of neurofeedback as a treatment module for ADHD.

The 6-month follow-up to this RCT was reported by Gevensleben et al (2010). Of the 94 children who completed treatment, 17 started medication during the follow-up interval, and parents of 16 children did not return the questionnaires. Follow-up was obtained in 61 (65%) children of the original per-protocol (n=102). Although the percentage of dropouts did not differ between groups, dropouts tended to have higher scores on the FBB-HKS, particularly in the control group. This difference in dropouts between groups limits the interpretation of the comparative data because scores in the 2 groups included in follow-up were dissimilar at baseline (e.g., baseline FBB-HKS score, 1.50 for the neurofeedback group vs 1.37 for the control group). The improvement observed in the neurofeedback group after treatment appeared to be preserved at six-month follow-up. For example, the inattention subscore of the FBB-HKS improved from 2.02 to 1.51 after treatment and remained at 1.49 at 6-month follow-up (moderate effect size [ES], 0.73). The hyperactivity/impulsivity subscore improved from 1.10 to 0.79 after treatment and remained at 0.76 at 6-month follow-up (small ES=0.35).

Steiner et al (2014) randomized 104 children ages 7 to 11 years with ADHD to neurofeedback, cognitive training, or a no-intervention control condition in an elementary school. Both the neurofeedback and cognitive therapies were administered with commercially available computer programs (45-minute sessions 3 times a week), monitored by a trained research assistant. The neurofeedback EEG sensor was embedded in a standard bicycle helmet with the grounding and reference sensors located on the chin straps on the mastoids. There were some small differences in baseline measures between groups. The slope of the change in scores over time was compared. Children in the neurofeedback group showed a small improvement on the Conners 3-Parent Assessment Report (ES=0.34 for inattention, ES=0.25 for executive functioning, ES=0.23 for hyperactivity/impulsivity), and subscales of the Behavior Rating Inventory of Executive Function-Parent Form (Global Executive Composite, ES=0.23) compared with baseline.
Interpretation of these findings is limited by the use of a no-intervention control group and lack of parental blinding. Evaluator-blinded classroom observation (using Behavioral Observation of Students in Schools software) found no sustained change with a linear growth model but significant improvement with a quadratic model. No between-group difference in change in medication was observed at the six-month follow-up.

**RCTs Not Included in the Meta-Analysis**

Several RCTs not included in the Cortese systematic review are described below.6,7,8.

Bink et al (2015) compared neurofeedback with treatment as usual in a nonblinded multicenter RCT.7 The comparator was broad and included the use of stimulant medication and behavioral interventions such as cognitive-behavioral therapy and counseling for patients or their parents. Adolescents with clinical ADHD symptoms were stratified by age and randomized to theta/ sensorimotor rhythm neurofeedback plus treatment as usual (n=59) or treatment as usual only (n=31). Treatment as usual could include stimulant medication and behavioral interventions such as cognitive-behavioral therapy and counseling for patients or their parents. These treatments were comparable between groups. Neurofeedback sessions were given 2 to 3 times a week for 25 weeks. Primary outcomes included the ADHD Rating Scale, Youth Self Report, and Child Behavior Checklist. Behavioral problems decreased equally for both groups, and neurofeedback plus standard treatment was not more effective than treatment as usual alone. Follow-up at one-year after treatment also found no benefit of neurofeedback when administered in combination with treatment as usual.

Gelade et al (2016) reported on a randomized comparison of neurofeedback (n=39) with either stimulants (n=36) or physical activity (n=37).8 Neurofeedback and physical activity were balanced for the number and duration of sessions (3 sessions a week for 10-12 weeks). The trial was adequately powered to detect a medium ES. Intention-to-treat analysis with last observation carried forward showed an improvement in parent-reported behavior for all interventions, while teachers, who were not blinded to treatment, reported a decrease of ADHD symptoms only for the methylphenidate group compared with placebo.

Alegria et al (2017) investigated the efficacy of real-time functional magnetic resonance neurofeedback (rtfMRI-NF) in adolescents with ADHD.10 This single-blind RCT consisted of 31 boys with ADHD (12-17 years old) who, over 2 weeks, underwent an average of 11 rtfMRI-NF sessions. The boys were assigned to rtfMRI-NF testing of the right inferior prefrontal cortex (n=18) or to a control group (n=13);testing of the left parahippocampal gyrus. The rtfMRI-NF testing sessions were visually engaging, and patients were asked to interact with the visuals but given very little coaching. Feedback was provided through video and images. Another session without feedback tested learning retention. The primary outcome measure was the ADHD Rating Scale, Version IV, a standard tool for assessing ADHD symptoms according to the Diagnostic and Statistical Manual of Mental Disorders;11 the secondary outcome measure was the revised Conners' Parent Rating Scale for ADHD. Both assessment tools were rated by parents. ADHD-related difficulties and functional impairments were assessed with the Weekly Parent Ratings of Evening and Morning Behavior-Revised and the Columbia Impairment Scale-Parent version, respectively. Active and control groups did not differ by type of ADHD-prescribed medication (p=0.3). Groups did not differ in their rtfMRI-NF performance score gain between final and baseline rtfMRI-NF testing sessions (mean prefrontal cortex score, 2.22; mean parahippocampal gyrus score, 10.00; p=0.43). Mean ADHD Rating Scale, Version IV scores were 36.72 and 37.77 in the prefrontal cortex and parahippocampal gyrus groups, respectively (p=0.78). This proof-of-concept study was limited by its sample size, population bias (only males), and rtfMRI-NF testing session completion rates.

In a triple-blind RCT conducted in Germany, Schönenberg et al (2017) identified 113 adults with ADHD and randomized them to neurofeedback (n=37) or sham neurofeedback (n=38) or metacognitive therapy (MCT; n=38).12 Patients in the neurofeedback group received 30 verum θ-to-β neurofeedback sessions over 15 weeks; sham neurofeedback patients received 15 sham sessions...
followed by 15 verum θ-to-β neurofeedback sessions over 15 weeks, and the MCT patients received 12 sessions over 12 weeks. Patients in the neurofeedback and sham neurofeedback groups were masked to treatment assignment; however, patients in the MCT group knew their treatment assignment. The primary outcome was symptom score on the Conners' Adult ADHD Rating Scale, which was measured before, during (week 8), and after treatment (at week 16 and at 6 months). At the 6-month follow-up, patients in all treatment groups reported a reduction in ADHD symptoms ($B = -2.58; 95\% \text{ confidence interval, } -3.48 \text{ to } -1.68; p<0.001$; neurofeedback vs sham neurofeedback, $B = -0.89; 95\% \text{ confidence interval, } -2.14 \text{ to } 0.37; p=0.168$; neurofeedback vs MCT, $-0.30; 95\% \text{ confidence interval, } -1.55 \text{ to } 0.95; p=0.639$). Reviewers concluded that neurofeedback training is not superior to sham or MCT but that all three treatments have merit in managing ADHD.

An RCT published by Sudnawa (2018) included 40 children with newly diagnosed ADHD in grades 1-6 and then randomized the cohort into 2 groups via block randomization (groups of 4) in an effort to determine the effectiveness of unipolar electrode neurofeedback (NF group, n=20) and using classical operant conditioning mechanisms. This allowed researchers to train participants to regulate brain activity by providing real-time feedback on EEG. A theta/beta protocol allows for the comparison of EEG-NF to methylphenidate (MPH group, n=20) for ADHD. An increase of beta waves and a reduction in theta activity is presumed an indicator of an increase in the patient’s attention span indicating a decrease in the ADHD symptomology. The NF group received 30 sessions and the MPH group were prescribed the medication for 12 weeks. Vanderbilt rating scales were completed by educators and parents to evaluate ADHD symptoms before and after treatments. The results of the analysis indicated no baseline differences in ADHD symptoms between groups. Post-treatment, educators reported significantly lower ADHD symptoms in the MPH group (P=0.01), but none between groups on the parents’ report (P=0.55). The ES was large in MPH (Cohen’s $d. 1.30-1.69$) while NF had a moderate ES (Cohen’s $d. 0.49-0.68$). The study was limited by the lack of placebo or sham group.

Section Summary: ADHD
At least 6 moderately sized RCTs (n range, 90-113 patients) have compared neurofeedback with methylphenidate, attention skills training, and/or cognitive therapy. These studies found either small or no benefit of neurofeedback. Studies using active controls have suggested that at least part of the effect of neurofeedback might be due to attention skills training, relaxation training, and/or other nonspecific effects. One RCT investigated neurofeedback in the right inferior prefrontal cortex. Another RCT assessed the utility of neurofeedback used to target the dorsal anterior cingulate cortex. All 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 an 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 patients with disorders other than ADHD.

The question addressed in this evidence review is: Does neurofeedback reduce symptoms and improve functional outcomes in patients with psychiatric, central nervous system, or pain disorders other than ADHD?

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

Patients
The relevant population of interest are individuals with disorders other than ADHD.
Interventions
The therapy being considered is neurofeedback.

Comparators
Comparators of interest include behavioral therapy and pharmacologic therapy. Treatment is actively managed by psychologists, psychiatrists, and primary care providers in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and QOL.

Table 3. Outcomes of Interest for Individuals with Disorders Other Than Attention-Deficit/Hyperactivity Disorder

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Details</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction of Symptoms as observed by parents</td>
<td>FBB-HKS completed by teachers and parent; 3-point growth model; Conners 3-Parent Assessment Report (Conners 3-P); Behavior Rating Inventory of Executive Function Parent Form (BRIEF); classroom observation (Behavioral Observation of Students in Schools); Wechsler Intelligence Scale for Children (WISC-III); Wechsler Adult Intelligence Scale (WAIS-III)</td>
<td>6 weeks</td>
</tr>
</tbody>
</table>

FBB-HKS: Fremdbeurteilungsbogen für Hyperkinetische Störungen.

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

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

Epilepsy
In a meta-analysis, Tan et al (2009) identified 63 studies on neurofeedback for treatment of epilepsy.14 Ten of the 63 studies met inclusion criteria; 9 of these studies included fewer than 10 subjects. The studies were published between 1974 and 2001 and used a pre/post design in patients with epilepsy refractory to medical treatment; only 1 controlled study was included. Meta-analysis showed a small ES for treatment (-0.233), with a likelihood of publication bias based on funnel plot. Updated literature searches have not identified any recent RCTs on the treatment of epilepsy with neurofeedback.

Substance Abuse
A systematic review by Sokhadze et al (2008) of neurofeedback as a treatment for substance abuse disorders described difficulties in assessing the efficacy of this and other substance abuse treatments.15 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 three 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.
Pediatric Brain Tumor Survivors
De Ruiter et al (2016) reported on a multicenter, triple-blinded RCT of neurofeedback in 80 pediatric brain tumor survivors who had cognitive impairments. 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 six-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.

Other Disorders
Literature searches and a systematic review by Schoenberg et al (2014) assessing biofeedback for psychiatric and neurologic disorders 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
- Depression
- Depression, pain, or fatigue in patients with multiple sclerosis
- Depression in alcohol addiction
- Dissociative identity disorder
- Fibromyalgia
- Insomnia
- Headache
- Childhood obesity
- Obsessive-compulsive disorder
- Parkinson disease
- Posttraumatic stress disorder
- 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-analysis. The relevant outcomes are symptoms, functional outcomes, and QOL. At least 6 moderately sized RCTs (n range, 90-113 patients) have compared neurofeedback with methylphenidate, attention skills training, and/or cognitive therapy. These trials found either small or no benefit of neurofeedback. 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 are more likely to be reported by evaluators unblinded to treatment (parents) than by evaluators blinded (teachers) to treatment, suggesting bias in the nonblinded evaluations. A meta-analysis also found no effect of neurofeedback on objective measures of attention and inhibition. Additional research with blinded evaluation of outcomes is needed to demonstrate an effect of neurofeedback on attention-deficit/hyperactivity disorder. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have disorders other than ADHD (e.g., epilepsy, substance abuse, pediatric brain tumors) who receive neurofeedback, the evidence includes case reports, case series, comparative cohorts, and small RCTs. The relevant outcomes are symptoms, functional outcomes, and QOL. 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements

American Academy of Pediatrics
The AAP (2011) published clinical practice guidelines on the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents.36 The AAP stated that although electroencephalogram biofeedback is used clinically, it is not approved by the U.S. Food and Drug Administration for the treatment of ADHD and requires further research. The AAP (2012) revised its position on biofeedback, designating it as a “Level 1 - Best Support” treatment for children with ADHD.35 The AAP (2014) further supported its position, stating that neurofeedback “can contribute to lasting improvements” for children with ADHD,36 citing the Steiner et al (2014)5 article.

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2013) issued guidance on management and support of children on the autism spectrum.37 The Institute stated that the number of treatments were considered but are not recommended, including neurofeedback.

International Society for Neurofeedback & Research

American Psychological Association
The American Psychological Association has provided general information on biofeedback (including neurofeedback) on its website, stating that “Biofeedback helps treat some illness, may boost performance, helps people relax and is even used to help children with Attention Deficit-Hyperactivity Disorder.”38

American Academy of Child and Adolescent Psychiatry and American Psychiatric Association
No information on neurofeedback was identified from the American Academy of Child and Adolescent Psychiatry or the American Psychiatric Association.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.
Table 4. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02991781 Multidisciplinary Tools for Improving the Efficacy of Public Prevention Measures Against Smoking</td>
<td>140</td>
<td>Jun 2019</td>
<td></td>
</tr>
<tr>
<td>NCT01841151 Does Neurofeedback and Working Memory Training Improve Core Symptoms of ADHD in Children and Adolescents? A Comparative, Randomized and Controlled Study</td>
<td>220</td>
<td>Dec 2018</td>
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<td>NCT01879644 Neurofeedback Study ADHD</td>
<td>120</td>
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<td>NCT02251743 Double-Blind 2-Site Randomized Clinical Trial of Neurofeedback for ADHD</td>
<td>142</td>
<td>Apr 2020</td>
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<td>NCT01883765 Efficacy of a Neurofeedback Treatment in Adults With ADHD: a Triple-blind Randomized Placebo-controlled Study</td>
<td>118</td>
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<td>NCT02146495 Pain and Sleep Quality Measures Before and After a Course of EEG Neurofeedback in Fibromyalgia Patients</td>
<td>200</td>
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<td>NCT02397161 Improving Mental Attention, Timing of Muscle Activation and Reactive Balance Control in Children With Developmental Coordination Disorder: A Randomized Controlled Trial</td>
<td>172</td>
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<td>NCT02778360 Effectiveness of a Personalized Neurofeedback Training Device (ADHD@Home) as Compared With Methylphenidate in the Treatment of Children and Adolescents With Attention-Deficit/ Hyperactivity Disorder: A Multicentre Randomized Clinical Study</td>
<td>179</td>
<td>Sep 2017</td>
<td></td>
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</table>

NCT: national clinical trial.  
* Denotes industry-sponsored or cosponsored trial.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Neurofeedback. TEC Assessments 1997; Volume 12; Tab 21.


**Documentation for Clinical Review**

- No records required

**Coding**

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

**IE**

The following services may be considered investigational.

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<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>CPT&lt;sup&gt;®&lt;/sup&gt;</td>
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<td>Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with</td>
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<td>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</td>
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<td>Biofeedback training by any modality</td>
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**Policy History**

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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>09/30/2014</td>
<td>BCBSA Medical Policy adoption</td>
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<tr>
<td>04/01/2016</td>
<td>Policy revision without position change</td>
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</table>

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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

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

**Prior Authorization Requirements (as applicable to your plan)**

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

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.
Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.