



United Behavioral Health

Behavioral Clinical Policy: Neurofeedback/Biofeedback For Behavioral And Substance Use Disorders

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INTRODUCTION

Behavioral Clinical Policies are a set of objective and evidence-based behavioral health criteria used by medical necessity plans to standardize coverage determinations, promote evidence-based practices, and support members' recovery, resiliency, and wellbeing for behavioral health benefit plans that are managed by Optum®¹.

INSTRUCTIONS FOR USE

This guideline is used to make coverage determinations as well as to inform discussions about evidence-based practices and discharge planning for behavioral health benefit plans managed by Optum. When deciding coverage, the member's specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member's benefits prior to using this guideline. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this guideline and the member's specific benefit, the member's specific benefit supersedes this guideline. Other clinical criteria may apply. Optum reserves the right, in its sole discretion, to modify its clinical criteria as necessary using the process described in *Clinical Criteria*.

This guideline is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Optum may develop clinical criteria or adopt externally-developed clinical criteria that supersede this guideline when required to do so by contract or regulation.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member-specific benefit plan document and any federal or state mandates, if applicable.

¹ Optum is a brand used by United Behavioral Health and its affiliates.

DESCRIPTION OF SERVICE

Neurofeedback/biofeedback therapy use real-time physical sign monitors, such as electroencephalographs (EEGs), heart-rate variability/respiratory sinus arrhythmia (HRV/RSA), and functional real-time functional magnetic resonance imaging (rtfMRI) to teach individuals how to control physiologic functions and mental states. As the individual's EEG pattern or other physiological process improves or is learned through the feedback, symptoms of ADHD or other behavioral disorders are expected to improve (Begemann et al., 2016).

In some instances, neurofeedback and quantitative electroencephalography (qEEG) are used in combination. When this occurs, the individual's EEG pattern is analyzed by qEEG, and an individualized feedback protocol is defined for the individual based on the reported findings (Begemann et al., 2016).

COVERAGE RATIONALE

Neurofeedback or biofeedback (with or without EEG guidance) is unproven and not medically necessary for treating individuals with any behavioral or substance use disorder, including but not limited to:

- Attention-deficit/hyperactivity disorder (ADHD)
- Depression
- Anxiety
- Obsessive-compulsive disorder
- Post-traumatic stress disorder
- Alcohol/drug abuse
- Autism spectrum disorder

The reviewed evidence, including randomized controlled trials and systematic reviews, does not clearly demonstrate a treatment effect of neurofeedback/biofeedback on symptoms of ADHD. Many of these reviewed studies contained a number of significant limitations. Additionally, there is a lack of well-designed clinical trials with sufficient sample sizes demonstrating the effectiveness of neurofeedback/biofeedback in the treatment of other behavioral and substance use disorders.

CLINICAL EVIDENCE

Clinical Trials & Studies

Attention-Deficit/Hyperactivity Disorder (ADHD)

Schönenberg et al. (2017) conducted a triple-blind randomized controlled trial (RCT) that identified 118 adults with ADHD and randomized them to neurofeedback (n=37) or sham neurofeedback (n=38) or meta-cognitive therapy (MCT; n=38). The neurofeedback group received 30 sessions over 15 weeks; the sham neurofeedback group received 15 sham sessions over 15 weeks; the meta-cognitive therapy group received 12 sessions over 12 weeks. Participants were ages 18-60 years. Participants in the neurofeedback and sham neurofeedback groups were masked to treatment assignment; however, subjects in the MCT group knew their treatment assignment. The primary outcome was symptom score on the Conners' Adult ADHD Rating Scale. At the 6-month follow-up, participants in all treatment groups reported a reduction in ADHD symptoms. Reviewers concluded that neurofeedback training is not superior to sham or MCT but that all 3 treatments have merit in managing ADHD. Larger, multicenter RCTs are needed to confirm these results.

Janssen and colleagues (2016) conducted a randomized controlled trial to compare the effects of neurofeedback (NF), methylphenidate (MPH), and physical activity (PA) in children diagnosed with ADHD. All participants were stimulant free for at least 1 month upon entry into the study. The study used a multicenter three way parallel group RCT design, enrolling a total of 112 children, all between the ages of 7 and 13. A computerized random number generator established the randomization. Results found that the MPH group showed a specific increase in P3 amplitude (demonstrating improved response inhibition) when compared to the NF and PA groups. The authors note that their finding of stimulants being the lone treatment to demonstrate significant improvement in response inhibition was in line with recent doubts on efficacy and specificity of NF as a treatment for ADHD.

Other Behavioral Disorders

In a double-blind, placebo-controlled, RCT, Young et al. (2017) examined the therapeutic efficacy of real-time functional MRI neurofeedback (rtfMRI-nf) training directed at increasing the amygdala's hemodynamic response to positive memories in adults with depression. A total of 36 unmedicated

adults with depression were randomly assigned to receive two sessions of real-time functional MRI neurofeedback (rtfMRI-nf) either from the amygdala (N=19) or from a parietal control region not involved in emotional processing (N=17). Twelve participants in the amygdala rtfMRI-nf group, compared with only two in the control group, had a >50% decrease in Montgomery-Åsberg Depression Rating Scale (MADRS) score. Six participants in the experimental group, compared with one in the control group, met conventional criteria for remission at study end. In participants receiving amygdala rtfMRI-nf, the percent of positive specific memories recalled increased relative to baseline and to the control group. The authors concluded that rtfMRI-nf training to increase the amygdala hemodynamic response to positive memories significantly reduced depressive symptoms and increased the percent of specific memories recalled on an autobiographical memory test. The small sample size and the short follow-up (1 week) in this study limit the generalizability of the findings. Further testing in larger samples that include medicated individuals is necessary to determine the subpopulations or characteristics for efficacy of this intervention.

Fielenbach et al. (2018) conducted an RCT to investigate the effects of a theta/sensorimotor rhythm (SMR) neurofeedback training protocol on levels of impulsivity, levels of drug craving, and actual drug intake in a population of forensic psychiatric patients with a diagnosis of substance use disorders (SUD). A total of 21 participants received 20 sessions of theta/SMR neurofeedback training in combination with treatment-as-usual (TAU). Findings of the intervention were compared with results from 21 participants who received TAU only. SMR magnitude showed a significant ($P=.02$) increase post training for patients in the neurofeedback training group, whereas theta magnitude did not change ($P=.71$). The described amount of drug craving as well as scores on the motor subscale of the Barratt Impulsivity Scale-11 decreased equally for patients in the neurofeedback training group and the TAU group. Other measures of impulsivity as well as drug intake did not change posttreatment. The results demonstrate that neurofeedback+TAU was not more effective than TAU only. The authors concluded that this study demonstrated evidence that forensic psychiatric patients are able to increase SMR magnitude over the course of neurofeedback training. However, at the group level, the increase in SMR activity was not related to any of the included impulsivity or drug craving measures. The authors stated that further research should address which patients would potentially benefit from neurofeedback training at an early stage of the employed training sessions.

Penzlin et al. (2015) conducted a randomized controlled study (RCT) showing that short-term heart rate variability (HRV) biofeedback in addition to standard rehabilitation care for alcohol dependence can reduce craving, anxiety and improve cardiovascular autonomic function. In a follow-up study, Penzlin et al. (2017) evaluated whether completion of 2-week HRV-Biofeedback training is associated with long-term abstinence. A survey was conducted on abstinence in adult participants with alcohol dependence 1 year after completion of the RCT comparing HRV-biofeedback in addition to inpatient rehabilitation treatment alone (controls). Abstinence rates were compared and analyzed for association with demographic data as well as psychometric and autonomic cardiac assessment before and after completion of the biofeedback training. Twenty-seven of the 48 participants completed the one-year follow-up. When including in the analysis only participants who completed follow-up, the rate of abstinence tended to be higher in those who underwent HRV-biofeedback 1 year earlier compared to those who received rehabilitative treatment alone (66.7% vs 50%). This non-significant trend was also observed in the intention-to-treat analysis where participants who did not participate in the follow-up were assumed to have relapsed (46.7% biofeedback vs. 33.3% controls). Neither cardiac autonomic function nor psychometric variables were associated with abstinence 1 year after HRV-biofeedback. The authors concluded that this follow-up study suggests that HRV-biofeedback might contribute to long-term abstinence when applied in addition to rehabilitation care. Because the trends observed in this study did not reach statistical significance, further research is required to confirm this hypothesis in a larger study population.

Systematic Reviews & Meta-Analyses

Attention-Deficit/Hyperactivity Disorder (ADHD)

Lambez et al. (2020) performed a meta-analysis on 18 studies published between 1980 and 2017 regarding the neuropsychological effects of non-pharmacological interventions for ADHD. The interventions within the studies were categorized into four categories: neurofeedback, cognitive-behavioral therapy, cognitive training, and physical exercises. The findings revealed that all

interventions demonstrated homogeneous and significant results; neurofeedback showed a moderate effect size of 0.61 ($df=5$, 95% CIL= -3.77, 4.82). The authors report an overall positive effect of psychological interventions on ADHD cognitive symptomology; this analysis supports the inclusion of non-pharmacological interventions in combination with the pharmacological treatments. The authors acknowledge limitations of this meta-analysis as a small number of studies met the strict inclusion criteria; the majority of studies included mixed groups of participants who were taking stimulant medication during the intervention and testing period; the notable results found in this study are limited to laboratory tasks. There were numerous quality intervention studies that were not included in this analysis due to their lack of computerized or written neuropsychological tests. The authors conclude that further research should focus on comparing randomized clinical trials while differentiating between medicated and nonmedicated participants.

Van Doren et al. (2019) conducted a systematic review and meta-analysis to evaluate neurofeedback (NF) in children with ADHD. The review investigated effects of NF after treatment and during 2–12 months post-treatment follow up period, in which no additional neurofeedback sessions or booster sessions were performed. A total of ten studies met inclusion criteria with 10 studies in the NF arm ($n = 256$) and 9 studies in the control arm ($n = 250$). The authors concluded that compared to non-active control treatments, NF appears to have more durable treatment effects, for at least 6 months following treatment. The authors indicated that carefully designed RCTs with longer follow-up time periods are needed before definite treatment recommendations can be provided.

Razoki (2018) performed a systematic review aimed to evaluate the efficacy of neurofeedback (NF) compared to stimulant medication in treating children and adolescents with ADHD. The review examined 8 randomized controlled trials that compared an NF condition, either alone or combined with medication. The age of participants ranged from 6-24 years across the 8 studies. The number of NF (theta/beta or theta/SMR) sessions ranged from 20 to 40, and the duration per session ranged from 25 to 50 minutes across the studies. The sample sizes were from $n=32$ to $n=130$. Results revealed that when only trials are considered that include probably blinded ratings or those that are sham-NF or semi-active controlled, or those that utilized optimally titration procedures, the findings do not support theta/beta NF as a standalone treatment for children or adolescents with ADHD. Nevertheless, an additive treatment effect of NF was observed on top of stimulants and theta/beta NF was able to decrease medication dosages, and both results were maintained at 6-month follow-up. The authors concluded that the role of NF in treating children diagnosed with ADHD should be considered as complementary in a multimodal treatment approach, individualized to the child, and may be considered a viable option to stimulants for a specific group of patients. Future research should further explore the possibility of NF reducing medication dosages. In addition, future research should prioritize which particular group of patients that may benefit from NF treatment.

A meta-analysis conducted by Cortese and colleagues (2016) examined the effects of neurofeedback (NF) on ADHD symptoms and neuropsychological deficits in RCTs in children and adolescents diagnosed with ADHD. The authors included 13 RCTs, totaling 520 participants with ADHD. Trials in which medication was part of normal clinical provision in either the control or active arm were permitted. Outcome measures included ADHD symptoms and neuropsychological laboratory-based measures. There was a small-to-moderate effect found on inattention, impulsivity/hyperactivity and total ADHD symptoms when proximal assessments were the outcome. However, the effects dropped to non-statistically significant levels for total ADHD and inattention symptoms in sensitivity analyses considering only trials with active/sham controls. When “probably blinded” outcomes were included in the analysis, effect size for outcomes decreased further, and none were significant. The authors concluded that the evidence from RCTs currently fails to support neurofeedback as an effective treatment for ADHD. Future research should address identifying the correct electrophysiological treatment target; expanding the use of standard EEG and learning protocols; developing new approaches to maximize the chances that neurofeedback leads to learning at the brain level; identifying predictors of treatment response for individual patients.

A systematic review and double-blind placebo-controlled study conducted by Vollebregt and colleagues (2014) determined if EEG-neurofeedback improves neurocognitive functioning in children with ADHD. First, 10 randomized controlled trials, including a range of different sample sizes and control conditions, were examined. The neurofeedback protocol, as well as the duration, frequency, and number of sessions varied between studies. Three of the 10 studies reported significant improvement

on at least one neurocognitive variable for the neurofeedback condition superior to the control condition. The authors concluded that these studies had many methodological limitations and the majority failed to show positive neurocognitive effects of neurofeedback. Next, the authors conducted a double-blind, placebo-controlled treatment trial for children aged 8-15 with ADHD. Forty-one children were randomly allocated to EEG-neurofeedback (n = 22) or placebo-neurofeedback (n = 19) for 30 sessions, twice a week. Results from the trial found no significant treatment effect on any neurocognitive variables (sustained attention dots task, visuospatial sequencing, digit span WISC-III, Rey Auditory-Verbal Learning Test, instrumental learning task, time production task, time reproduction task). The authors conclude that the study failed to establish positive treatment effects on neurocognitive functioning after EEG-neurofeedback when compared to placebo-neurofeedback. The authors recommend that future research should concentrate on various methods to deliver neurofeedback.

Other Behavioral Disorders

Ferreira et al. (2019) conducted a systematic review and meta-analysis to assess the therapeutic efficacy of biofeedback in obsessive-compulsive and related disorders (OCD&RD) category (body dysmorphic, hoarding, trichotillomania, and excoriation disorders). Ten studies containing 102 OCD participants (three randomized controlled trials) mostly applying neurofeedback (one publication used thermal biofeedback) were included in the review. Five neurofeedback studies were selected for meta-analysis (89 patients; two randomized controlled trials). The authors found a beneficial effect of neurofeedback for OCD symptoms, but also found critical limitations on methodology, high heterogeneity among studies, and a reporting bias. Future research following high-quality guidelines with well-designed methodology are needed to address the efficacy of biofeedback approaches for OCD&RD.

Imperatori et al. (2018) conducted a systematic review to evaluate the effectiveness of biofeedback and neurofeedback for eating disorders (EDs) and EDs-related symptoms. Thirteen studies were included in the review. Neurofeedback was represented and investigated in 8 of the reviewed studies. The considered studies provide preliminary data of the usefulness of feedback-based techniques in the treatment of several dysfunctional eating behaviors (e.g., food craving, rumination). Due to the high heterogeneity of samples, outcome measures and feedback modalities, a meta-analysis in order to quantify the effectiveness of both biofeedback and neurofeedback was not performed. The results of this review suggest that feedback-based treatments may be useful in the treatment of several dysfunctional eating behaviors. The authors conclude that future well-designed studies with large clinical samples are needed in order to draw definitive conclusions.

Goessl et al. (2017) examined the effect of heart rate variability (HRV) biofeedback on symptoms of anxiety and stress by conducting a meta-analysis on 24 studies totaling 484 participants. The authors concluded that HRV biofeedback training is linked to a large reduction in self-reported stress and anxiety. However, well-controlled studies are required to determine if this intervention offers a beneficial approach for treating stress and anxiety with wearable devices.

Thibault et al. (2017) conducted a comprehensive review of the functional magnetic resonance imaging neurofeedback (fMRI-nf) literature and generated a systematic database of fMRI-nf findings. In total, 99 primary research experiments with number of subjects ranging from 6-80, met inclusion criteria. The authors found that the vast majority of fMRI-nf findings suggest that self-regulation of specific brain signatures seems feasible; however, replication of associated behavioral outcomes remains limited. The authors emphasize the need for double-blind placebo-controlled studies with rigorous and standardized statistical analyses to determine if this modality can produce meaningful behavioral improvements.

Begemann and colleagues (2016) conducted a meta-analysis of studies investigating the efficacy of EEG neurofeedback in the treatment of psychiatric disorders. A total of 30 studies were included (n = 1171) and evaluated neurofeedback for ADHD, autism, obsessive-compulsive disorder, generalized anxiety disorder and depression. The majority of studies included a passive-semi-active control group, with only three placebo-controlled trials identified. Twenty-one of the thirty studies used randomization procedures. The authors' analysis found small to medium effect sizes for treating the symptoms of ADHD, with varying results for its effect on other diagnoses. The authors conclude that a

lack of methodologically rigorous studies prevents evidence-based conclusions on the efficacy of EEG neurofeedback in the treatment of various psychiatric disorders. The authors recommend that future studies are carefully planned and implemented, including power calculations to establish required sample sizes, randomization, blinding and adequate control conditions, to assess whether neurofeedback reveals efficacy in the field of psychiatry.

Schoenberg and David (2014) conducted a systematic review to explore the current therapeutic use of biofeedback for a range of psychiatric disorders, including addictions, anxiety disorders, autism spectrum disorders, depressive disorders, dissociative disorders, personality disorders, and psychoses. A total of 63 articles were included in the review. EEG biofeedback was used in 32% of the reviewed studies; with 29% incorporating electromyographic (EMG), 16% heart rate variability (HRV) and/or sole respiration, 6% heart rate, 5% electrodermal (EDA) and 3% thermal biofeedback methodologies. Anxiety disorders were the most commonly treated among the reviewed studies (68%). The review found 81% of articles to report some level of clinical improvement related to biofeedback exposure, and 65% to a statistically significant level of symptom reduction. However, the review highlights a lack of standardization amongst biofeedback studies for psychiatric disorders, and methods/results sections were inconsistent in structure and lacking empirical detail, resulting in the exclusion of several studies from the review. The authors note that Level 1 ("not empirically supported") studies were not included in the review because of exclusion criteria, potentially skewing the overall evaluation of biofeedback treatments used in psychiatric domains. The authors conclude that further development of standardized controlled methodological protocols adapted for specific disorders and guidelines to produce comprehensive reports may contribute towards demonstrating the efficacy of biofeedback interventions within mainstream psychiatry.

Guidelines & Consensus Statements

American Academy of Pediatrics (AAP)

In the AAP's Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of ADHD in Children and Adolescents (2011), the section titled "Areas for Future Research" includes "study of medications and other therapies used clinically but not approved by the FDA for ADHD, such as electroencephalographic biofeedback."

The appendix to the AAP's Clinical Practice Guidelines for the Treatment of ADHD in Children and Adolescents (2011) states that alternative therapies for treatment of ADHD...include "large doses of vitamins, essential fatty acids, and other dietary alterations; chelation; and electroencephalographic (EEG) biofeedback". The appendix notes that there is "insufficient evidence to determine whether these therapies lead to changes in core symptoms of ADHD or function, and for many of them, there is limited information about their safety. For these reasons, these therapies cannot be recommended".

AAP guidance material titled "ADHD, What Every Parent Needs to Know" (2011) states that studies on the use of neurofeedback to date have been criticized for lacking appropriate controls or random assignment of test subjects to the treatment/sham treatment groups.

The Department of Veterans Affairs and Strauss et al. (2011) completed an evidence-based synthesis review of alternative therapies, such as biofeedback, for the treatment of PTSD. The authors conclude that there a lack of scientific evidence on the efficacy, adverse effects, indications, appropriate dosing, or mechanisms of action for therapies such as biofeedback and the treatment of PTSD.

U.S. FOOD AND DRUG ADMINISTRATION

Biofeedback/neurofeedback devices are considered a medical device when registered with the FDA. They are considered Class II devices and are exempt from 510(K) premarket notification requirements. See the following for more information:

FDA website: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5050>.

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare does not have a National Coverage Determination (NCD) specifically for neurofeedback or biofeedback (with or without EEG guidance) used in treating individuals with behavioral or substance use disorders. Local Coverage Determinations (LCDs) exist for CPT codes 90875 and 90876. Refer to

the LCDs for Outpatient Psychiatry and Psychology Services, Partial Hospitalization Programs and Psychiatry and Psychology Services.

Medicare has published NCD 30.1 Biofeedback Therapy and NCD 30.1.1 Biofeedback Therapy for the Treatment of Urinary Incontinence. Medicare states the biofeedback is covered only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions (www.CMS.gov).

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member-specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other clinical criteria may apply.

Procedure Codes	Description
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

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REVISION HISTORY

Date	Action/Description
12/16/2016	• Version 1 (Approved by UMC)
01/10/2018	• Annual Update: Updates to formatting, references, coding.
07/15/2019	• Annual Update: Updates to formatting, references.
06/15/2020	• Annual Review: updates to references/sourcing.