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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Neurobiofeedback & Brain Mapping

- Neurofeedback (EEG Biofeedback) and
- Neuropsychiatric EEG-Based Assessment Aid (NEBA) – ADHD
- Quantitative EEG (Brain Mapping)

Criteria

For Medicare Members

Source	Policy
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "*Attention Deficit Hyperactivity Disorder (ADHD)*"** for medical necessity determinations. Use the Non-Medicare Criteria below. Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "*Quantitative EEG (Brain Mapping)*"** for medical necessity determinations. Use the Non-Medicare Criteria below.

For Non-Medicare Members

Service	Criteria used
Neurofeedback for ADHD (biofeedback) Neuropsychiatric EEG-Based Assessment Aid (NEBA)	See MCG* A-0330: *Biofeedback Inconclusive or Non-Supportive Evidence* For attention-deficit hyperactivity disorder in children, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefits vs. harm; additional research is recommended. For adolescents, there is insufficient evidence in the published medical literature to show that this service/therapy provides better outcomes than current standard services/therapy. There was no literature reported for adults with attention-deficit hyperactivity disorder at the time of the review. *For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access
EEG, Quantitative (Brain Mapping)	**Effective until February 1, 2024** No review required **Effective February 1, 2024** Kaiser Permanente has elected to use the EEG, Quantitative (Brain Mapping) (A-1050) MCG* Care Guideline for medical necessity determinations. This is not covered per MCG*. For access to the

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	MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Attention Deficit Hyperactivity Disorder (ADHD) is a common chronic neurobehavioral condition affecting approximately 5% of children worldwide. A child with ADHD may present as: 1) predominantly hyperactive, 2) predominantly inattentive, or 3) both hyperactive and inattentive. ADHD is often accompanied by impaired social adjustment, academic problems, and lower adaptive functioning in major life activities which may persist to adolescence and adulthood (Benner-Davis 2007, Gevensleben 2009, Lansbergen 2011).

Medication, particularly psychostimulants, is the primary treatment for ADHD. Psychostimulants work quickly, improve attention, and reduce hyperactivity and impulsitivity in about 70% of all children. However, their effect on academic achievement, family relation, and social skills is small. There are also some concerns regarding their side effects, and their long-term benefits have not been established. Behavioral therapy has been shown to reduce ADHD symptoms, but may not be sufficiently effective especially in terms of generalization and long-term effects (Leins 2007, Gevensleben 2009, Lansbergen 2011).

In searching for additional or alternative treatments for children with ADHD, neurofeedback (NF) emerged as a promising option. NF is a type of biofeedback that uses electroencephalography (EEG) to provide a signal that can be used by a person to receive feedback about brain activity. It is based on the rationale that there is a relationship between surface EEG and the underlying thalamocortical mechanism responsible for its rhythms and frequency modulations. Lubar was the first to report on EEG and behavioral changes in a hyperkinetic child. He explained that ADHD children differ from others in that their brain waves tend to be of larger amplitude. Specifically, the EEG shows excess theta activity along with lower amounts of beta activity. This pattern of brain wave activity usually indicates a sleep or daydreaming state, rather than an alert and focused state. The goal of EEG biofeedback training is to alter these abnormal brain waves by decreasing theta waves, while simultaneously increasing beta waves (i.e. theta suppression/beta enhancement). This would potentially help the child acquire self-control over certain brain activity patterns, derive self-regulation strategies, and apply the gained self-regulation skills in daily life (Lubar 1976, Lubar 1991, Bakhshayesh 2011).

In EEG biofeedback training, the therapist explains to the child the connection between what is happening in his/her cortex and what is recorded on the EEG and helps him/her learn how to gain control over the brain activity patterns. The EEG biofeedback equipment is connected to the individual with sensors that are placed on the scalp and ears. Once connected, the brainwave activity can be observed on a computer monitor. Individuals are then taught to play computerized games using their brainwave activity. Changes in the individual's brainwave activity are then fed back to the individual through visual and/or auditory information by the computer. During a typical 45-minute session, the child is seated in front of a computer, electrodes are connected to his head, and then a therapist starts up a videogame or movie on the child's screen and monitors his brain waves on another screen. The child then locks his eyes on the action, concentrating on sending the kind of brain waves that will keep a virtual airplane flying, or perhaps a favorite movie rolling. If his attention wanders or he begins to fidget, the plane slows or the movie screen darkens, and the therapist encourages him to regain focus using techniques such as slow, deep breathing. Children may also practice maintaining learned brainwave states when engaged in school- or work-related tasks (Gevensleben 2009).
In the last three decades many studies compared brain activity using electro-encephalography (EEG) among children with ADHD versus the brain activity of normal controls in an attempt to study the underlying neurophysiology of

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ADHD; and to investigate subtypes of the disorder and their response to treatment. The EEG frequency bands of most interest in ADHD research are the theta, beta, and alpha bands either alone or in relation to one another such as the theta/beta power or amplitude ratio. Alpha band activity is typically observed during rest when the eyes are closed and is negatively associated with central nervous system arousal. Beta band activity on the contrary, generally accompanies mental activity and concentration. Cortical theta is observed frequently in young children, but in older children and adults, it tends to appear during meditative, drowsy, or sleeping states. Researchers suggest that most children with ADHD display EEG differences in their brain electrical activity as compared to normal children, particularly with respect to their increased frontocentral theta activity primarily during the resting state. This indicates decreased cortical activity that may be associated with underarousal. A theta /beta ratio (TBR) due to increased theta is reported by many investigators as a consistent characteristic of ADHD. Some groups recommend using the TBR during eyes-opened or eye-closed resting condition as an add-on for the diagnosis and monitoring of ADHD. However, it is reported that the true functional significance of this measure is still unknown, and an elevated theta activity may be a nonspecific marker of cortical dysfunction common to other disorders such as epilepsy, bipolar disorder, and polysubstance abuse (Arns 2013, Liechti 2013, Loo 2012).

A number of studies examined the accuracy and diagnostic value of the theta power and TBR in discriminating normal children from children with learning disorders, ADD, and ADHD. In 2005, Boutros and colleagues performed a review and meta-analysis to estimate the strength and effect size of increased theta activity in ADHD patients. Based on their findings they concluded that the increased EEG theta activity in ADHD is promising and should be further developed as a diagnostic test for ADHD. Around the same time another group of investigators (Snyder and Hall, 2006) also conducted a meta-analysis to investigate the theta and beta powers and their ration (TBR) and concluded that the pooled results support the finding that an increase in the theta/beta ratio is a commonly observed trait in ADHD relative to normal controls. They however, cautioned that theta/beta ratio trait may arise with other conditions, and that a prospective study covering differential diagnosis would be required to determine generalizability to clinical applications (Arns 2013, Boutros 2005, Loo 2012 Snyder 2006).

Based on this EEG technology, the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System (NEBA Health, Augusta, GA) was developed and recently received Food and Drug Administration (FDA), in July 2013, to help assess ADHD in children and adolescents 6-17 years of age. It is not to be used as a stand-alone diagnostic test, but as a conjunctive tool for diagnosing ADHD. NEBA is a non-invasive test that calculates the ratio of theta and beta waves frequencies in 15-20 minutes (FDA and NEBA websites accessed January 15, 2014).

According to the FDA, the use of the device together with the complete medical and psychological examination, can help confirm an ADHD diagnosis or a clinician's decision that further diagnostic testing should focus on ADHD or other medical or behavioral conditions that lead to symptoms similar to ADHD. The FDA reviewed the NEBA System through a de novo classification process, a regulatory pathway for some low- to moderate-risk medical devices that are not substantially equivalent to an already legally marketed device (FDA website accessed January 15, 2014).

Medical Technology Assessment Committee (MTAC)

Neurofeedback for ADHD

10/17/2011: MTAC REVIEW

Evidence Conclusion: A number of small randomized and nonrandomized controlled trials included in Arns and colleagues' meta-analysis (evidence table 1) and the pooled results of available data indicate that NF may have some beneficial effects on a number of ADHD measures. However, when compared with stimulant therapy, NF did not prove to have an equivalent or superior effect on ADHD core symptoms. None of the studies monitored potential adverse effects of NF. The small study sizes, their short duration, lack of a valid control group, mixed and multiple interventions used, lack of double-blinding, additional time spent with the therapists for NF, as well as other study methodological limitations make it hard to determine the efficacy of the neurofeedback used alone or in addition to other interventions for the treatment of children with ADHD. Gevensleben and colleagues' trial (evidence table 2) conducted by a group of researchers in a university hospital in Germany, compared NF training to computerized attention skills training. This may be considered as a more valid comparison as it controls for therapist time and attention training. The primary endpoint was improvement in attention and reduced hyperactivity as rated by the parents. No measures of children's academic functioning or classroom performance were collected. The results of the trial showed that symptoms improved in both groups; however, the score of the primary outcome measure (parents' rating of FBB-HKS [a German rating scale]) was significantly higher in children in the NF group. The trial was randomized and controlled, but was not blinded, and the NF training program was developed by the study group. After the training period 18% of the children were started on a medication. Six months follow-up data, available for only two thirds of the participants, showed that the behavioral

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improvements were maintained at 6 months, but the difference between the two interventions did not reach a statistically significant level. The investigators attributed the lack of significant difference to insufficient statistical power due to the smaller number of children with follow-up data. They authors concluded that NF training may help some children, but more research is needed to replicate the findings and identify which children with ADHD are more likely to benefit from NF training. Well conducted randomized trials with a sham neurofeedback control, double-blinding, and long-term follow-up are needed to establish the efficacy and safety of neurofeedback in improving the core symptoms of ADHD.
Articles: The search revealed one meta-analysis on the efficacy of neurofeedback treatment in ADHD and a number of RCTs that were included in the meta-analysis. Three small RCTs published after the meta-analysis, as well as a report on 6 months follow-up of an earlier RCT were also identified. The meta-analysis as well as the largest trial, which had a more valid design and longer follow-up, were selected for critical appraisal. Arns M, de Ridder S, Strehl U, et al. Efficacy of neurofeedback treatment in ADHD: the effects on inattention, impulsitivity and hyperactivity; a meta-analysis. Clin EEG Neurosci 2009; 40:180-189. See Evidence Table. Gevensleben H, Holl B, Albrecht B, et al. Is neurofeedback an efficacious treatment for ADHD? A randomized controlled trial. J Child Psychol Psychiatry. 2009; 50:780-789. See Evidence Table. Gevensleben H, Holl B, Albrecht B, et al. Neurofeedback training in children with ADHD: 6-month follow-up of a randomized controlled trial. Eur Child Adolesc Psychiatry 2010; 19:715-724. See Evidence Table.

The use of Neurofeedback for ADHD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/20/2016: MTAC REVIEW
Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD)
Evidence Conclusion: EEG-NF versus placebo, sham: EEG neurofeedback (EEG-NF) treatments in children with ADHD: an updated meta-analysis of randomized controlled trials: (Micoulaud-Franchi et al., 2014) (Evidence table 1) On parent assessment (probably unblinded assessment), the overall ADHD scores (-0.49 [-0.74, -0.24], $p < 0.001$) as well as the inattention and hyperactivity/impulsivity scores were significantly improved (-0.46 [-0.76, -0.15], $p = 0.003$); -0.34 [-0.59, -0.09], $p = 0.007$) in patients receiving EEG NF compared to controls. On teacher assessment (probably blinded assessment), only the inattention score was significantly improved (Effect size of -0.30 [-0.58, -0.03] with p=0.03). Based on the findings, EEG-NF may improve core ADHD symptoms. However, the major limitation lies in the heterogeneity of EEG-NF protocols across individual studies. Other limitations include: 1) the small number of studies, 2) small size of individuals RCTs, 3) the exclusion of relevant RCTs in the meta-analysis, 4) the lack of blinded parent assessment and 5) the lack of evaluation of study quality. These result in low quality of evidence. Due to the aforementioned limitations, result should be interpreted with caution. A randomized placebo-controlled trial of electroencephalographic (EEG) neurofeedback in children with attention-deficit/hyperactivity disorder (van Dongen-Boomsma et al., 2013) (Evidence table 2) In both groups, and based on investigator assessment, ADHD symptoms decreased over time ($F= 26.56$, $p < .001$) to a similar degree. According to teacher assessment, significant improvement of symptoms over time ($F= 13.54$, $p = .001$) was reported, without a difference between groups ($F= 0.45$, $p = .509$). On the CGI-I scale, symptoms did not worsen. On CGAS, score increased similarly in both groups ($F= 1.96$, $p = .169$).
On PSERS, the total number of adverse events decreased significantly over time ($F= 6.30$, $p = .016$) and decreased similarly in the two groups ($F= 0.10$, $p = .754$). The SDQ assessment showed that sleep problems decreased significantly over time ($F= 5.42$, $p = .025$) in both groups. Overall, no differences in improvements between the groups were reported. However, several limitations are worth noted: 1) the small sample size limiting statistical power; 2) the therapist was not blinded; 3) the use of medications by some participants could have biased the outcomes of NF; 4) no follow-up data was available to assess the short or long term effects of NF; 5) generalizability might have been compromised since the sample is composed of white children. Studies with larger sample size and long follow-up are warranted to confirm these findings. Neurofeedback versus stimulant Medication: Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Meisel et al., 2014) (Evidence table 3) Regarding pre-post comparison, ADHD symptoms and functional impairment improved in general in both groups. Academic performance was only improved (except for math and oral expression) in NF group. Concerning pre-follow-up comparisons, similar results were observed. NF group-maintained symptoms achievement at 2 & 6 months after treatment completion. Inattention improved more than hyperactivity/impulsivity across evaluators, time & treatment. The major limitations are the small sample size and lack of longer follow-ups. In addition, patients were not blinded, and allocation concealment was not discussed. The risk of bias is therefore high. However, no major differences in symptom improvement were observed. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Orem & Hestad, 2013) (Evidence table 4) After treatment, there was a significant difference between the two groups with improvement observed in the medication groups. There were significant differences after treatment between the groups on inattention, Visual Continuous Performance Test (VCPT) &
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reaction time measures on patient assessment. All were in favor of the medication groups. Similar findings were observed on teacher assessment. In addition, higher positive changes were observed with the medication groups. The results indicate that medication led to better symptoms control on both parent and teacher assessment, particularly on inattention, VCPT & reaction time measures and that NF did not produce positive changes. However, this pilot study has several limitations: 1) generalizability of the findings may have been compromised because of the non-use of standard protocols, 2) small sample size 3) blinding was not discussed, 4) 59% of patients had learning disabilities making harder to achieve a positive outcome. Overall, the risk of bias is high, and results should be interpreted with caution. A randomized controlled trial of combined EEG feedback and methylphenidate therapy for the treatment of ADHD (Li et al., 2013) (Evidence table 5) In terms of Core symptoms and behavioral problems, significant improvement was noted for combination group compared to the control group. For social function assessments, the combination group performance was significantly better than that of the control group after 40 sessions of treatment ($p < 0.001$). Regarding brain function assessment, the dominant probability of 8 Hz wave decreased significantly in the combination group. Adverse events correlate with methylphenidate dosage. The authors conclude that the combination of neurofeedback and methylphenidate is effective in improving the symptoms of ADHD in children. They also demonstrated that this combination is superior in enhancing core symptoms, behavioral issues, and brain function. However, limitations reside in small sample size limiting statistical power; the lack of long-term follow-up. One of the authors had financial tie with the Janssen Pharmaceutical. Therefore, results should be interpreted with caution.

Additional study: A placebo-controlled neurofeedback study (Arnold et al., 2012) did not demonstrate superiority of NF on ADHD core symptoms.

Conclusion:

- The body of evidence is of low quality.
- Variations in the characteristics of EEG-NF protocols, the use of medications while receiving NF treatment, the small sample size, the lack of blinding in a number of studies and the short follow-up periods may have biased the findings.
- Neurofeedback may improve the core symptoms of ADHD in children but did not demonstrate superiority or was not equivalent to pharmacological therapy in reducing ADHD symptoms in children.
- There is insufficient evidence to determine whether Neurofeedback in combination with methylphenidate is effective in reducing the core symptoms of ADHD in children.

Articles: The literature revealed a number of articles, but the following articles were selected for critical appraisal: EEG neurofeedback treatments in children with ADHD: an updated meta-analysis of randomized controlled trials (Micoulaud-Franchi et al., 2014) See Evidence table 1. A randomized placebo-controlled trial of electroencephalographic (EEG) neurofeedback in children with attention-deficit/hyperactivity disorder (van Dongen-Boomsma, Vollebregt, Slaats-Willemse, & Buitelaar, 2013) See Evidence table 2. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Meisel, Servera, Garcia-Banda, Cardo, & Moreno, 2014) See Evidence table 3. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Ogrim & Hestad, 2013) See Evidence table 4. A randomised controlled trial of combined EEG feedback and methylphenidate therapy for the treatment of ADHD (Li, Yang, Zhuo, & Wang, 2013) See Evidence table 5.

The use of Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Neuropsychiatric EEG-Based Assessment Aid (NEBA)

02/10/2014: MTAC REVIEW

Evidence Conclusion: There is no published evidence to date to determine the safety, accuracy, or clinical utility of NEBA system in discriminating between children with or without ADHD. The FDA approval was based on a clinical study of 275 children and adolescents with attention and/or behavioral concerns. The study was conducted by the manufacturer of the NEBA system and has not been published in a peer reviewed journal to date. The observational studies on the correlation between the theta/beta ratios (TBR) had their limitations, and their results were inconclusive. In addition (according to Loo, 2012) there are wide variation in EEG instrumentation that can make it very hard to compare or generalize results of studies using different EEG hardware and software.

Articles: The literature search did not reveal any published study on the NEBA system; it only identified several observational studies that investigated brain activity using EEG in children with ADHD compared with normal controls, as well as three meta-analyses that pooled the results of a number of these studies.

The use of NEBA does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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Biofeedback—

Considered Not Medically Necessary:

CPT® Codes	Description
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, 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 (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
90901	Biofeedback training by any modality
95812	Electroencephalogram (EEG) extended monitoring; 41-60 minutes
95813	Electroencephalogram (EEG) extended monitoring; 61-119 minutes
95816	Electroencephalogram (EEG); including recording awake and drowsy
95819	Electroencephalogram (EEG); including recording awake and asleep
Dx Codes	**Description**
F90.0-F90.9	Attention-deficit hyperactivity disorder

Brain Mapping—

Considered Not Medically Necessary:

CPT® Codes	Description
95961	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by a physician or other qualified health care professional
95962	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of attendance by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
95999	Unlisted neurological or neuromuscular diagnostic procedure
S8040	Topographic brain mapping

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
11/01/2011	11/01/2011[MDCRPC], 10/02/2012[MDCRPC,] 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	09/05/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/20/2016	Added Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD) MTAC review
08/10/2016	Merged NEBA criteria into same document

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09/06/2016	Added KPWA policy for Medicare members
10/03/2017	MPC approved to adopt MCG A-0330 summary of findings as criteria language
09/05/2023	MPC approved to adopt EEG, Quantitative (Brain Mapping) MCG A-1050. Requires a 60-day notice; effective February 1, 2024.

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