3.01.03	Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder, Cognitive Impairment, or Autism Spectrum Disorder		
Original Policy Date:	February 1, 2016	**Effective Date:**	December 1, 2025
Section:	3.0 Mental Health	**Page:**	Page 1 of 18

Policy Statement

I. Quantitative electroencephalographic-based assessment of the theta/beta ratio is considered **investigational** as a diagnostic aid for attention-deficit/hyperactivity disorder.

II. Quantitative electroencephalographic-based assessment is considered **investigational** as a diagnostic aid for cognitive impairment.

III. Quantitative electroencephalographic-based assessment is considered **investigational** as a diagnostic aid for autism spectrum disorder.

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

Policy Guidelines

Coding

See the Codes table for details.

This testing would likely be reported with existing electroencephalography CPT codes. The clinician would report the appropriate code for electroencephalography (e.g., 95812-95813) and the code for digital analysis of electroencephalogram (95957) would be reported for the analysis.

Description

Patients with attention-deficit/hyperactivity disorder (ADHD) may have alterations in their brain wave patterns that can be measured by quantitative electroencephalography (EEG). A commercially available system, the Neuropsychiatric EEG-based ADHD Assessment Aid, measures the resting theta/beta ratio of the electroencephalogram. This technology is being evaluated to aid in the diagnosis of ADHD in adolescents and children for whom there is a clinical suspicion of ADHD. Quantitative EEG is also being evaluated to aid in the diagnosis of other disorders such as in individuals with cognitive impairment (e.g., dementia) and autism spectrum disorder.

This evidence review does not address the use of quantitative EEG in epilepsy or emergent intraoperative settings.

Summary of Evidence

For individuals suspected of having attention-deficit/hyperactivity disorder (ADHD) who received quantitative electroencephalography (EEG), the evidence includes a number of studies on brain wave patterns, particularly the theta/beta ratio. Relevant outcomes are symptoms, functional outcomes, and medication use. Numerous studies have evaluated brain wave patterns with standard EEG equipment, and a pivotal trial, submitted to the U.S. FDA, measured the theta/beta ratio with the

Neuropsychiatric EEG-based ADHD Assessment Aid system. In the pivotal trial, both the specificity and positive predictive value of quantitative EEG were high. The reclassification analysis would suggest that a negative Neuropsychiatric EEG-based ADHD Assessment Aid might make ADHD less likely, although it is not clear from this study whether the consensus diagnosis was more accurate than the initial clinical diagnosis that included patient interview and parent rating scales. The larger body of evidence also raises questions about the utility of measuring the theta/beta ratio because it has not been a consistent finding across studies. Given the uncertainty of an increase in the theta/beta ratio in patients with ADHD, additional study is needed to determine whether a low theta/beta ratio can identify children and adolescents who are unlikely to have ADHD. Also, the effect of the test on patient outcomes would allow greater certainty regarding the usefulness of this test. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals suspected of having cognitive impairment (e.g., dementia) who receive quantitative electroencephalography (EEG), the evidence includes an observational study. Relevant outcomes are symptoms and functional outcomes. One study found quantitative EEG poorly diagnosed Alzheimer's disease (AD). Another study evaluating quantitative EEG for diagnosing dementia and dementia with Lewy bodies (DLB) demonstrated a sensitivity of 80% and a specificity of 89% for diagnosing dementia, and a sensitivity of 60% and a specificity of 90% for diagnosing DLB. This study had a small sample size and was conducted at a single center. There is limited evidence on the brain wave patterns that associated with cognitive impairment. Therefore, additional study is needed to determine the brain wave patterns that can identify individuals with cognitive impairment. Also, the effect of the test on patient outcomes would allow greater certainty regarding the usefulness of this test. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals suspected of having autism spectrum disorder (ASD) who receive quantitative electroencephalography (EEG), the evidence includes a systematic review and meta-analysis. Relevant outcomes are symptoms and functional outcomes. One systematic review with meta-analyses showed that autistic individuals had reduced relative alpha power (g=-0.35) and increased gamma power (absolute: g=0.37, relative: g=1.06) compared to neurotypical individuals. This systematic review did not report on sensitivity or specificity. There is limited evidence on the brain wave patterns that associated with ASD. Therefore, additional study is needed to determine the brain wave patterns that can identify individuals with ASD. Also, the effect of the test on patient outcomes would allow greater certainty regarding the usefulness of this test. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Not applicable

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services 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 law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

In 2011, the generic device Neuropsychiatric Interpretive Electroencephalograph Assessment Aid was granted a de novo 510(k) classification and cleared for marketing by the U.S. Food and Drug Administration (FDA; class II, special controls, product code: NCG). According to the FDA documentation, a neuropsychiatric interpretive EEG assessment aid is a device prescribed by a physician that uses a patient's electroencephalogram to provide an interpretation of the patient's neuropsychiatric condition. In addition to the general controls, approval of these devices is subject to a number of special controls, including the following:

- Clinical performance testing must demonstrate the accuracy, precision, and reproducibility of the EEG-based interpretation, including any specified equivocal ones (cutoffs).
- Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value, and negative predictive value per the device intended use. Repeatability of measurement must be demonstrated using interclass correlation coefficients and illustrated by qualitative scatterplots.
- The device design must include safeguards to prevent device use as a stand-alone diagnostic.
- The labeling must bear all information required for the safe and effective use of the device.

In 2013, the Neuropsychiatric EEG-based Assessment Aid (NEBA ; NEBA Health previously Lexicor Medical Technology) for ADHD was granted a de novo 510(k) classification and cleared for marketing by the FDA (K112711). The device is indicated to measure the theta/beta ratio of the electroencephalogram at electrode CZ on patients 6 to 17 years of age, combined with a clinician's evaluation, to aid in the diagnosis of ADHD. NEBA should only be used by a clinician as confirmatory support for a completed clinical evaluation or as support for the clinician's decision to pursue further testing following clinical evaluation. The device is not intended as a stand-alone tool in the evaluation or diagnosis of ADHD. FDA product code: NCG

In 2017, the eVox System (Evoke Neuroscience, Inc.) was granted 510(k) classification and cleared for marketing by the FDA (K171781; FDA Product Codes: GWQ, GWJ). In 2020, the NeuralScan System was granted 510(k) classification and cleared for marketing by the FDA (K192753; FDA Product Codes: OLT, GWJ, GWQ). Both of these devices are indicated for: "the acquisition, display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP) obtained by placing two or more electrodes on the head to aid in diagnosis." These indications are not condition- or disease-specific.

Rationale

Background

Attention-Deficit/Hyperactivity Disorder

Attention-deficit/hyperactivity disorder (ADHD) is common in children, adolescents, and adults, and is defined by pervasive symptoms of inattention and/or hyperactivity-impulsivity, which lead to impairment in at least 2 domains of the work, school, or home environments. Stimulant medications reduce symptoms associated with ADHD, although there are concerns about the potential for overdiagnosis and overprescribing of medication.

Diagnosis

Presently, ADHD is diagnosed clinically by assessing behavioral symptoms and impairment via interviews and standard questionnaires. Diagnosis can be challenging because the core symptoms are nonspecific. They may be present in other psychiatric disorders (e.g., learning disabilities, conduct disorders, affective disorders) or result from environmental influences such as a lack of discipline. Also, ADHD is a heterogeneous disorder with multiple subtypes and frequently coexists with other psychiatric disorders.

There has been substantial research conducted over the last several decades on whether electroencephalography (EEG)-derived brain wave patterns in patients with ADHD differ from those without ADHD. EEG patterns are typically categorized into 4 frequency ranges: delta (<4 Hz), theta (4-7 Hz), alpha (8-12 Hz), and beta (13-25 Hz). The largest focus of research on brain wave patterns in ADHD has been on whether there are increased theta wave activity and an increased theta/beta ratio in ADHD patients.

The Neuropsychiatric EEG-based ADHD Assessment Aid (NEBA®) system is a specific quantitative EEG system that measures the resting theta/beta ratio of the electroencephalogram with an electrode located at the central midline position (referred to as position CZ in the international 10-20 EEG system). Quantitative EEG uses computer analysis with the mathematical transformation from the time domain into the frequency domain (fast-Fourier transform) to determine the total power at each frequency. The relative power of the waveform can then be calculated in relation to the total power of the 4 frequency ranges. The NEBA system uses proprietary cutoffs to generate an estimate of the likelihood of ADHD based on the resting theta/beta ratio.

It is proposed that the NEBA system can be used to confirm a clinical diagnosis or support further testing in children and adolescents with ADHD. The system is not intended to evaluate patients for whom the clinician's diagnosis of ADHD is negative, and the system does not generate an interpretive report in this situation. It is also proposed that the clinician's diagnostic impression plus the results generated by the NEBA system may reduce the potential for overdiagnosis of ADHD, and thereby reduce the risks of administering unnecessary pharmacologic therapy in the intended-use population. Also, as a result of research on EEG brain waves in ADHD, neurofeedback has been developed as a potential treatment for ADHD (see evidence review 2.01.28). This treatment employs principles of biofeedback using EEG brain wave activity and attempts to alter the brainwave patterns in beneficial ways.

Cognitive Impairment

Dementia is characterized by the decline in cognition in one or more cognitive domains, such as learning and memory, language, executive function, complex attention, perceptual-motor, and social cognition. Alzheimer Disease (AD) is the most common form of dementia in older adults. AD is a fatal neurodegenerative disease that causes progressive loss in memory, language, and thinking, with the eventual loss of ability to perform social and functional activities in daily life. Survival after a diagnosis of dementia due to AD generally ranges between 4 and 8 years; however, life expectancy can be influenced by other factors, such as comorbid medical conditions. It is estimated that 6.2 million Americans aged 65 and older are currently living with AD dementia, and the number is projected to reach over 12 million by 2050, with an approximate lifetime risk of developing AD dementia at age 65 of 21.1% for women and 11.6% for men.[1,] The lifetime risk for dementia due to AD is approximately 20% for women and 10% for men. Per the 2018 American Academy of Neurology practice guideline update on mild cognitive impairment (MCI), the prevalence of MCI was 6.7% for ages 60 to 64, 8.4% for ages 65 to 69, 10.1% for ages 70 to 74, 14.8% for ages 75 to 79, and 25.2% for ages 80 to 84.[2,] The cumulative dementia incidence was 14.9% in individuals with MCI >65 years of age followed for 2 years.

Data from the National Institute on Aging have shown that Black Americans are approximately 1.5 to 2 times more likely to develop AD and related dementias as compared to Whites.[3] Additionally, Black participants in AD research studies were 35% less likely to be diagnosed with AD and related dementias and were found to have more risk factors for the disease as well as greater cognitive impairment and symptom severity than White participants. Findings from 2 national surveys conducted by the Alzheimer's Association also found that people of color face discrimination when seeking health care for AD and related dementias with the highest level of discrimination in dementia health care reported by Black Americans (50%) followed by Native (42%), Asian (34%), and Hispanic (33%) Americans.[4] Non-Hispanic White Americans reported a discrimination rate of 9%.

Diagnosis

Presently, dementia is diagnosed clinically through initial cognitive testing followed by a physical examination including neurological examination, and then subsequent laboratory testing and neuroimaging (e.g., computed tomography (CT) or magnetic resonance imaging MRI). According to The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), criteria for major neurocognitive disorder (e.g., dementia), include the following[5]:

- "Evidence of significant cognitive decline from a previous level of performance in one or more cognitive domains (complex attention, executive function, learning and memory, language, perceptual-motor, or social cognition) based on:
    - Concern of the individual, a knowledgeable informant, or the clinician that there has been a significant decline in cognitive function; and
    - A substantial impairment in cognitive performance, preferably documented by standardized neuropsychological testing or, in its absence, another quantified clinical assessment.
- The cognitive deficits interfere with independence in everyday activities (i.e., at a minimum, requiring assistance with complex instrumental activities of daily living such as paying bills or managing medications).
- The cognitive deficits do not occur exclusively in the context of a delirium.
- The cognitive deficits are not better explained by another mental disorder (e.g., major depressive disorder, schizophrenia)."

Autism Spectrum Disorder

Autism spectrum disorder (ASD) is a biologically based neurodevelopmental disorder characterized by persistent deficits in social communication, social interaction and restricted, repetitive patterns of behavior, interests, and activities. ASD can range from mild social impairment to severely impaired functioning. As many as half of individuals with autism are non-verbal and have symptoms that may include debilitating intellectual disabilities, inability to change routines, and severe sensory reactions. The American Psychiatric Association's DSM-5 provides standardized criteria to help diagnose ASD.[5] Autism can co-occur with mental health diagnoses, including, but not limited to, depression, anxiety disorders (e.g., social anxiety, obsessive-compulsive disorder), attention deficit hyperactivity disorder, Tourette syndrome/tic disorder, personality disorder, and/or psychosis.[6]

Diagnosis

Diagnosis of ASD in the United States (U.S.) generally occurs in 2 steps: developmental screening followed by comprehensive diagnostic evaluation if screened positive. The American Academy of Pediatrics (AAP) recommends general developmental screening at 9, 18, and 30 months of age and ASD-specific screening at 18 and 24 months of age.[7,8] Diagnosis and intervention in the first few years of life can have a strong impact on functioning since it allows for treatment during a key window of developmental plasticity.[9,10] However, early diagnosis in the US remains an unmet need even though studies have demonstrated a temporal trend of decreasing mean age at diagnosis over time.[11,12]

Literature Review

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Quantitative Electroencephalography in Suspected Attention-Deficit/Hyperactivity Disorder

Clinical Context and Test Purpose

Attention-deficit/hyperactivity disorder (ADHD) is common in children, adolescents, and adults, and is defined by pervasive symptoms of inattention and/or hyperactivity-impulsivity, which lead to impairment in at least 2 domains of the work, school, or home environments. Stimulant medications reduce symptoms associated with ADHD, although there are concerns about the potential for overdiagnosis and overprescribing of medication.

The purpose of quantitative electroencephalography (EEG) in individuals who are suspected of having ADHD is to inform a decision whether to initiate specific therapy.

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

Populations

The relevant population of interest is individuals with suspected ADHD.

Interventions

The test being considered is quantitative EEG, using the Neuropsychiatric EEG-based ADHD Assessment Aid (NEBA) system, as part of a clinical evaluation. Devices that provide neurofeedback are also able to assess the theta/beta ratio with quantitative analysis.

Comparators

The following practice is currently being used to diagnose ADHD: clinical evaluation alone.

Outcomes

The general outcomes of interest are patient symptoms, functional outcomes, and medication use.

Study Selection Criteria

For the evaluation of the clinical validity of the tests, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described;
- Included a validation cohort separate from development cohort.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

A number of studies have measured theta activity or the theta/beta ratio in children and adolescents with ADHD compared with nonaffected controls. The most commonly reported alteration in EEG is an increase in the theta/beta ratio. However, some studies have reported that other patterns (e.g., increased beta wave activity) are found in some patients, and several recent studies have found no significant difference in theta activity in a clinical versus nonclinical population. Quantitative reports of EEG used in the adult ADHD population have found no consistent evidence of atypical theta/beta ratios as a marker of ADHD.[13,]

A TEC Assessment (2014) evaluated the evidence related to the use of quantitative EEG with the NEBA system in the diagnosis of ADHD.[14,] This evidence was submitted to the U.S. Food and Drug Administration (FDA) in 2013 and subsequently published by Snyder et al (2015).[15,16,] The evidence on the accuracy of NEBA in the diagnosis of ADHD is described next. The evidence also included a discussion of the technical performance of NEBA for the diagnosis of ADHD and test-retest reliability of the NEBA theta/beta ratio for EEG data from 198 patients who had recordings on 2 different days. Evidence of the technical performance is beyond the scope of this evidence review. No studies were identified that assessed whether the reclassification of patients suspected of having ADHD, as reported to the FDA, improved health outcomes.

Cohort Studies

Data submitted to the FDA regarding the diagnostic accuracy of the NEBA system were from the multicenter study of 275 children and adolescents (aged 6-18 years, described above) who presented with attention and/or behavioral concerns to 1 of 13 clinics in the U.S.[15,16,] An additional 89 children and adolescents were recruited but did not complete the study, and, of these, 67 had incomplete EEG recordings.[16,] Diagnostic evaluation for ADHD and other disorders was conducted with a clinical interview and rating scales that included behavior rating scales, IQ and achievement testing, and scales of severity and dysfunction. A consensus best-estimate diagnosis was determined by a multidisciplinary clinical team composed of a clinical psychologist, a neurodevelopmental pediatrician, and a child/adolescent psychiatrist. The clinical team had access to deidentified patient files; however, they did not interview patients or have access to the parent rating scales, features considered critical for a criterion standard diagnosis of ADHD. A separate group of investigators who were unaware of the clinical diagnosis collected the EEG data (NEBA system). When compared with the consensus diagnosis, NEBA had a sensitivity of 89%, a specificity of 87%, a positive predictive value of 81%, and negative predictive value of 93% for adolescents (aged 12-17 years). For children (ages 6-11 years), NEBA had a sensitivity of 79%, a specificity of 97%, a positive predictive value of 96%, and negative predictive value of 82%. The investigators calculated that the addition of NEBA to the clinician's ADHD evaluation would have increased the clinician's diagnostic accuracy from 61% to 88%. This calculation is based on the 275 patients who completed the protocol, rather than the intention-to-treat population. The results of this FDA-regulated study suggested that quantitative EEG might be used to decrease the overdiagnosis of ADHD by identifying patients who may not have the disorder. Strengths of this study included its multicenter design and the reclassification analysis of data obtained from a blinded analysis. Limitations were lack of patient interview by the consensus team and lack of intention-to-treat analysis.

Snyder et al (2008) also reported on the accuracy of the theta/beta ratio for the diagnosis of ADHD in an industry-sponsored, investigator-blinded, multicenter study.[17,] Patients (N=159) aged 6 to 18 who had presented to 1 of 4 psychiatric and pediatric clinics with suspected attention and behavioral symptoms were evaluated in a standardized semi-structured manner according to *Diagnostic and Statistical Manual of Mental Disorders, 4th edition* (DSM-IV) criteria by a clinical team trained on the study instruments. Rating scales were distributed to parents and teachers and held in sealed envelopes until the blind was broken. An EEG was collected separately by investigators, who were blinded to the clinical diagnosis, using a 19-electrode cap according to the 10-20 system with eyes open and eyes shut. A threshold of 1.5 standard deviations of the theta/beta ratio from normative

database values (according to age) at electrode CZ was used to determine ADHD versus non-ADHD. With a prevalence of ADHD of 61% based on clinical diagnosis, the theta/beta ratio had a sensitivity of 87%, a specificity of 94%, a positive predictive value of 95%, and negative predictive value of 82%. The rating scales provided a sensitivity of 38% to 79% and specificity of 13% to 61%. Results from this study were used to set a new theta/beta threshold for an analysis of data from the FDA-regulated study of the NEBA device.[15,16,]

Other studies have reported lower accuracy of quantitative EEG in the diagnosis of ADHD. van Dijk et al (2020) assessed whether different signal processing methods affected the ability to distinguish patients with ADHD from controls.[18,] Five different signal processing algorithms were applied to EEG screening data from 2 multi-center clinical studies: the International Collaborative ADHD Neurofeedback multisite clinical trial and the International Study to Predict Optimized Treatment in ADHD. The 2 studies included 608 children with ADHD and 158 children without ADHD. van Dijk et al found significant differences in the theta/beta ratio calculated with the 5 algorithms, but none of the methods were able to distinguish between children with and without ADHD. A limitation of this study is that methods used by NEBA were not specifically assessed.

Section Summary: Clinically Valid

Patients who have ADHD may have altered brain wave patterns on quantitative EEG compared with patients without ADHD. The most common alteration reported in clinical studies is an increased theta/beta ratio; however, not all studies have found this association. With regard to use of the NEBA system as part of a clinical evaluation, no studies have reported on sensitivity and specificity. In the pivotal study of the NEBA system, investigators calculated that the addition of NEBA to the clinician's ADHD evaluation was estimated to increase diagnostic accuracy from 61% to 88%. However, there are limitations to the pivotal study including lack of an intention-to-treat approach and no patient interviews conducted by the consensus team. Additionally, a recent study of various EEG processing methods in a large dataset found no diagnostic value of the theta/beta ratio for children with ADHD, raising questions about the utility of quantitative EEG in the diagnosis of ADHD.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

A proposed benefit of the NEBA system is a reduction in the overdiagnosis of ADHD, thereby lessening the risks of unnecessary pharmacologic therapy in children and adolescents. There were no published studies that directly reported on clinical outcomes, such as measures of disease activity and/or medication use.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Cohort Studies

The pivotal FDA study reported on the reclassification of diagnosis following NEBA may be considered an indirect measure that may impact outcomes.

The evidence related to whether quantitative EEG improves the clinical diagnosis of patients with suspected ADHD consists of the material submitted to the FDA as part of the NEBA's approval process and subsequently published by Snyder et al (2015), as previously described.[15,16,] The study included reclassification tables to demonstrate whether NEBA provides additional information beyond the clinician's initial diagnosis, which is summarized in Table 1. Use of NEBA was consistent with the categorization of patients diagnosed with ADHD by both the initial clinical diagnosis and the consensus diagnosis. For example, 95 (73%) of 130 children and adolescents who were considered to have ADHD by the consensus diagnosis were classified as ADHD by both the clinician alone and NEBA. Reclassification was observed when using NEBA for patients diagnosed by clinician alone as ADHD and consensus as non-ADHD. For example, 145 children and adolescents had a non-ADHD diagnosis by the consensus. Of the 145, 93 had received an initial clinical diagnosis of ADHD but 85 (91%) were negative by NEBA.

Table 1. NEBA Reclassification of Patients With Consensus ADHD Diagnosis

Consensus Diagnosis[a]			Initial Clinical Diagnosis		Total
ADHD			+	-	
	NEBA interpretation[b]	+	95 (81.9)	11 (78.6)	106
		-	21 (18.1)	3 (21.4)	24
	Total		116	14	130
Not ADHD			+	-	
	NEBA interpretation[b]	+	8 (8.6)	1 (1.9)	9
		-	85 (91.4)	51 (98.1)	136
	Total		93	52	145

ADHD: attention-deficit hyperactivity disorder; FDA: U.S. Food and Drug Administration; NEBA: Neuropsychiatric EEG-Based Assessment Aid.

[a] The consensus diagnosis is assumed to be the reference standard (i.e., correct). Two categories are included in the ADHD consensus diagnosis: diagnosed with ADHD or referred for more testing for the condition. Similarly, the "not ADHD" diagnosis included those diagnosed as not having ADHD or as needing more testing for other conditions.

[b] The NEBA interpretation is a composite of both the initial clinical diagnosis and the NEBA results, like a dichotomized posttest probability. The performance measures are presumably calculated assuming that a negative NEBA result can override a positive initial clinical diagnosis, but in the FDA summary, it was stated that a negative diagnosis can only result from a negative initial clinical diagnosis (i.e., the NEBA interpretation cannot override it).

Section Summary: Clinically Useful

Patients who have ADHD may have altered brain wave patterns on quantitative EEG compared with patients without ADHD. While an increased theta/beta ratio is the most common alteration reported, not all studies have found this association. No studies have reported on the sensitivity and specificity of the NEBA system when added to clinical diagnosis. In the pivotal study, diagnostic accuracy was estimated to increase from 61% to 88% when added to clinical diagnosis. However, there are limitations to the pivotal study, and a recent study of various EEG processing methods in a large dataset found no diagnostic value of the theta/beta ratio for children with ADHD, raising questions about the utility of quantitative EEG in the diagnosis of ADHD. Reclassification results from the pivotal trial suggest that NEBA may support an alternative diagnosis in patients initially suspected of having ADHD but not confirmed by consensus diagnosis. No studies were identified that addressed whether clinical outcomes were improved for patients with suspected ADHD who were reclassified by NEBA.

Quantitative Electroencephalography in Suspected Cognitive Impairment

Clinical Context and Test Purpose

The purpose of quantitative electroencephalography (EEG) in individuals who are suspected of having is to inform a decision whether to initiate specific therapy.

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

Populations
The relevant population of interest is individuals with suspected cognitive impairment.

Interventions
The test being considered is quantitative EEG as part of a clinical evaluation. Devices that provide neurofeedback are also able to assess the theta/beta ratio with quantitative analysis.

Comparators
The following practice is currently being used to diagnose cognitive impairment: clinical evaluation and neuroimaging (e.g., computed tomography (CT) or magnetic resonance imaging MRI).

Outcomes
The general outcomes of interest are patient symptoms, functional outcomes, and medication use.

Study Selection Criteria
For the evaluation of the clinical validity of the tests, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described;
- Included a validation cohort separate from development cohort.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence
There is limited evidence for the use of quantitative EEG in the diagnosis of cognitive impairment such as dementia. Iannaccone et al (2023) evaluated the effectiveness of quantitative EEG for diagnosing dementia and dementia with Lewy bodies (DLB).[19,] Patients with suspected initial state of dementia or cognitive impairment (n=32) and controls (n=16) were recruited for the study. Participants underwent clinical assessment by 2 blinded neurologists, EEG recording, and a 6-month follow-up clinical assessment. The use of quantitative EEG demonstrated a sensitivity of 80% and a specificity of 89% for diagnosing dementia, and a sensitivity of 60% and a specificity of 90% for diagnosing DLB. This study had limitations including its retrospective, single-center design. More evidence is needed to determine whether quantitative EEG can be used as a diagnostic tool for cognitive impairment.

Ommundsen et al (2011) conducted a study evaluating the use of quantitative EEG in diagnosing Alzheimer's disease (AD).[20,] They compared quantitative EEG results with clinical diagnoses (N=104). Quantitative EEG yielded a positive test in 22 of 30 patients with a clinical diagnosis of AD and a negative test in 34 of 74 patients without AD. The authors concluded that quantitative EEG was poor at diagnosing AD due to the frequency of false-positive results.

Section Summary: Clinically Valid
Individuals with cognitive impairment such as dementia may have altered brain wave patterns on quantitative EEG compared to individuals without cognitive impairment. However, there is limited evidence of the validity of quantitative EEG used to diagnose cognitive impairment. One study found quantitative EEG poorly diagnosed AD. Another study evaluating quantitative EEG for diagnosing dementia and DLB demonstrated a sensitivity of 80% and a specificity of 89% for diagnosing

dementia, and a sensitivity of 60% and a specificity of 90% for diagnosing DLB. This study was retrospective and conducted at a single center.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Section Summary: Clinically Useful
Individuals with cognitive impairment such as dementia may have altered brain wave patterns on quantitative EEG compared to individuals without cognitive impairment. However, since there is limited evidence of the validity of quantitative EEG used to diagnose cognitive impairment, inferences cannot be made about clinical utility. One study found quantitative EEG poorly diagnosed AD. Another study evaluating quantitative EEG for diagnosing dementia and DLB demonstrated a sensitivity of 80% and a specificity of 89% for diagnosing dementia, and a sensitivity of 60% and a specificity of 90% for diagnosing DLB. This study was retrospective and conducted at a single center. No studies have demonstrated that quantitative EEG improves diagnostic accuracy in individuals with cognitive impairment.

Quantitative Electroencephalography in Suspected Autism Spectrum Disorder
Clinical Context and Test Purpose
The purpose of quantitative electroencephalography (EEG) in individuals who are suspected of having is to inform a decision whether to initiate specific therapy.

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

Populations
The relevant population of interest is individuals with suspected autism spectrum disorder (ASD).

Interventions
The test being considered is quantitative EEG as part of a clinical evaluation. Devices that provide neurofeedback are also able to assess the theta/beta ratio with quantitative analysis.

Comparators
The following practice is currently being used to diagnose ASD: developmental screening followed by comprehensive diagnostic evaluation if screened positive.

Outcomes
The general outcomes of interest are patient symptoms, functional outcomes, and medication use.

Study Selection Criteria
For the evaluation of the clinical validity of the tests, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described;
- Included a validation cohort separate from development cohort.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence
There is limited evidence for the use of quantitative EEG in the diagnosis of ASD. Neo et al (2023) conducted 10 meta-analyses, including 41 studies, to examine differences in resting-state EEG power across various frequency bands (delta, theta, alpha, beta, and gamma) in autistic individuals (n=1246) compared to neurotypical individuals (n=1455).[21,] The results showed that autistic individuals had reduced relative alpha power (g=-0.35) and increased gamma power (absolute: g=0.37, relative: g=1.06) compared to neurotypical individuals. There were no significant differences in delta, theta, absolute alpha, and beta power between the 2 groups. The study also found substantial heterogeneity in effect sizes across all frequency bands. Moderator analyses indicated that factors such as age, biological sex, IQ, referencing scheme, epoch duration, and use of gold-standard autism diagnostic instruments did not influence the effect sizes. However, the type of resting-state paradigm (eyes-closed vs. eyes-open) and recording duration did moderate some effect sizes. These findings suggest that resting-state alpha and gamma power could be potential biomarkers for autism. This systematic review did not report on sensitivity or specificity.

Section Summary: Clinically Valid
Individuals with ASD may have altered brain wave patterns on quantitative EEG compared to individuals without ASD. However, there is limited evidence of the validity of quantitative EEG diagnosing ASD. One systematic review with meta-analyses showed that autistic individuals had reduced relative alpha power (g=-0.35) and increased gamma power (absolute: g=0.37, relative: g=1.06) compared to neurotypical individuals. This systematic review did not report on sensitivity or specificity.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Section Summary: Clinically Useful
Individuals with ASD may have altered brain wave patterns on quantitative EEG compared to individuals without ASD. However, since there is limited evidence of the validity of quantitative EEG diagnosing ASD, inferences cannot be made about clinical utility. One systematic review with meta-analyses showed that autistic individuals had reduced relative alpha power (g=-0.35) and increased

gamma power (absolute: g=0.37, relative: g=1.06) compared to neurotypical individuals. This systematic review did not report on sensitivity or specificity. No studies have demonstrated that quantitative EEG improves diagnostic accuracy in individuals with ASD.

Supplemental Information

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

Practice Guidelines and Position Statements

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

American Academy of Neurology

In 2016, the American Academy of Neurology released a technology report on quantitative electroencephalography for ADHD.[22,] The main conclusion of the report was that it remains "unknown whether a combination of standard clinical examination and EEG [electroencephalography] theta/beta power ratio increases diagnostic certainty of ADHD compared with clinical examination alone."

in 2017, the American Academy of Neurology released a consensus report on the diagnosis and management of dementia with Lewy bodies (DLB).[23,] Quantitative EEG was listed as a supportive biomarker, defined as "biomarkers consistent with DLB that help the diagnostic evaluation, but without clear diagnostic specificity." They acknowledged building evidence for quantitative EEG, showing prominent posterior slow-wave EEG activity with periodic fluctuations in the pre-alpha/theta range, as a biomarker for DLB.

American Academy of Pediatrics

The 2019 American Academy of Pediatrics' practice guidelines on the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder (ADHD) was based on a systematic review from the Agency for Healthcare Research and Quality.[24,] The guidelines indicated that to make a diagnosis of ADHD, the primary care clinician should determine that *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, Text Revision*, criteria have been met (including documentation of impairment in more than 1 major setting), and information should be obtained primarily from reports from parents or guardians, teachers, and other school and mental health clinicians involved in the child's care. The primary care clinician should also rule out any alternative cause (quality of evidence B/strong recommendation). Assessment by quantitative electroencephalography was not mentioned in these guidelines.

In 2020, the American Academy of Pediatrics published a clinical report on the identification, evaluation, and management of children with ASD.[8,] The guidelines state: "EEG is not recommended as a routine baseline evaluation in the absence of clinical concern about seizures, atypical regression, or other neurologic symptoms on history or examination that would suggest an EEG is indicated."

American College of Radiology

In 2019, the American College of Radiology's Appropriateness Criteria for dementia did not include quantitative EEG in their list of imaging.[25,]

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 ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05635318	Quantitative EEG Neurofeedback as an Add-on Therapy For Attention-deficit/Hyperactivity Disorder (ADHD)	102	Jan 2024 (not yet recruiting)
NCT05406778[a]	SPARK Neuro Quantitative Resting State EEG Protocol for Assessing Cognitive Impairment and AD Status 'REMIND' Study	800	Nov 2025 (recruiting)
NCT06068361	Diagnostic Evaluation of Dementia with Lewy Bodies Using a Multimodal Approach: EEG, Cognitive, Biological and MRI Biomarkers	130	Sep 2027
Unpublished			
NCT03644043[a]	Quantitative EEG for Assessment of Mild Cognitive Impairment Associated With Preclinical Alzheimer's Disease - Evidence for Amyloid Indication Study	2000	Nov 2020 (unknown status)
NCT05406778[a]	SPARK Neuro Quantitative Resting State EEG Protocol for Assessing Cognitive Impairment and AD Status 'REMIND' Study	185 (actual)	Jan 2024 (actual)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	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
	95957	Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)
HCPCS	None	

Policy History

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

Effective Date	Action
02/01/2016	BCBSA Medical Policy Adoption
06/01/2017	Policy revision without position change
12/01/2017	Policy revision without position change
12/01/2018	Policy revision without position change
12/01/2019	Policy revision without position change
12/01/2020	Annual review. No change to policy statement. Literature review updated.
12/01/2021	Annual review. No change to policy statement. Literature review updated.
12/01/2022	Annual review. No change to policy statement. Literature review updated.
12/01/2023	Annual review. No change to policy statement. Literature review updated.
12/01/2024	Annual review. Policy statement, guidelines and literature review updated. Policy title changed from Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder to current one.
12/01/2025	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

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

Investigational or Experimental: Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

A. The technology must have final approval from the appropriate government regulatory bodies.
   - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
   - Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
   - The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

C. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

D. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established alternatives.

E. The improvement must be attainable outside the investigational setting.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

Feedback

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

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

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

Disclaimer: 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 member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder, Cognitive Impairment, or Autism Spectrum Disorder 3.01.03 **Policy Statement:** I. Quantitative electroencephalographic-based assessment of the theta/beta ratio is considered **investigational** as a diagnostic aid for attention-deficit/hyperactivity disorder. II. Quantitative electroencephalographic-based assessment is considered **investigational** as a diagnostic aid for cognitive impairment. III. Quantitative electroencephalographic-based assessment is considered **investigational** as a diagnostic aid for autism spectrum disorder.	**Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder, Cognitive Impairment, or Autism Spectrum Disorder 3.01.03** **Policy Statement:** I. Quantitative electroencephalographic-based assessment of the theta/beta ratio is considered **investigational** as a diagnostic aid for attention-deficit/hyperactivity disorder. II. Quantitative electroencephalographic-based assessment is considered **investigational** as a diagnostic aid for cognitive impairment. III. Quantitative electroencephalographic-based assessment is considered **investigational** as a diagnostic aid for autism spectrum disorder.