LOUISIANA BLUE

Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder, Cognitive Impairment, or Autism Spectrum Disorder

Policy # 00444
Original Effective Date: 12/16/2015
Current Effective Date: 03/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers quantitative electroencephalographic-based assessment of the theta/beta ratio as a diagnostic aid for attention deficit/hyperactivity disorder (ADHD) to be **investigational.***

Based on review of available data, the Company considers quantitative electroencephalographic-based assessment as a diagnostic aid for cognitive impairment to be **investigational.***

Based on review of available data, the Company considers quantitative electroencephalographic-based assessment as a diagnostic aid for autism spectrum disorder to be **investigational.***

Background/Overview

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 two domains of the work, school, or home environments. Stimulant medications reduce symptoms associated with ADHD, although there are concerns about the potential for over diagnosis 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 (eg, 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.

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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. 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. 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. 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. 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. 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 (eg, 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 (eg, dementia), include the following:

- "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. Autism can co-occur with mental health diagnoses, including, but not limited to, depression, anxiety disorders (eg, social anxiety, obsessive-compulsive disorder), attention deficit hyperactivity disorder, Tourette syndrome/tic disorder, personality disorder, and/or psychosis.

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. 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. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 (eg, 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 (eg, 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.

Supplemental Information

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. 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). 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. 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. 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.

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 1.

Table 1. 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)
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)

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

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Policy History

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12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. New Policy.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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12/05/2024 Medical Policy Committee review
12/11/2024 Medical Policy Implementation Committee approval. Title changed from "Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder" to "Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder, Cognitive Impairment, or Autism Spectrum Disorder." Indications added for the use of quantitative EEG as a diagnostic aid for cognitive impairment and autism spectrum disorder with investigational policy statements.
Next Scheduled Review Date: 12/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	95700, 95705, 95706, 95707, 95708, 95709, 95710, 95711, 95712, 95713, 95714, 95715, 95716, 95717, 95718, 95719, 95720, 95721, 95722, 95723, 95724, 95725, 95726, 95812, 95813, 95816, 95819, 95957
HCPCS	No codes
ICD-10 Diagnosis	F70-F79, F84.0, F84.9, F90.0-F90.9, G31.84

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.