Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder

Policy #: 572
Latest Review Date: October 2023
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **quantitative electroencephalographic-based assessment of the theta/beta ratio** as a **non-covered benefit** and as **investigational** as a diagnostic aid for attention-deficit/hyperactivity disorder.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

Attention Deficit/Hyperactivity Disorder

Attention deficit/hyperactivity disorder (ADHD) is a common disorder in children, adolescents, and adults 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 over prescribing of medication.

Diagnosis

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

There has been a substantial amount of research over the last several decades on whether EEG-derived brain wave patterns in patients with ADHD differ from those without ADHD. EEG patterns are typically categorized into four 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 is increased theta wave activity and an increased theta/beta ratio in ADHD patients.

The NEBA® system is a specific quantitative EEG system (QEEG) that measures the resting theta/beta ratio of the EEG with an electrode located at the central midline position (referred to

as position CZ in the international 10-20 EEG system). QEEG uses computer analysis with mathematical transformation from the time domain into the frequency domain (fast Fourier transform) to determine the total power at each frequency. Relative power of the waveform can then be calculated in relation to the total power of the four frequency ranges. The NEBA system uses proprietary cut offs 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 in 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 over diagnosis of ADHD, and thereby reduce the risks of administering unnecessary pharmacologic therapy in the intended use population. In addition, because of research on EEG brain waves in ADHD, neuro-feedback 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 brain wave patterns in beneficial ways.

KEY POINTS:

The most recent literature update was performed through August 29, 2023.

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 brainwave 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.

Practice Guidelines and Position Statements

American Association of Pediatrics

The 2019 American Association of Pediatrics' practice guidelines for the diagnosis, evaluation, and treatment of ADHD by the American Association of Pediatrics (AAP) state 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 one 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 is not mentioned in these guidelines.

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

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

KEY WORDS:
NEBA, Neuropsychiatric EEG-based assessment aid, Brain function test for ADHD, Lexicor QEEG system

APPROVED BY GOVERNING BODIES:
In 2011, the U.S. Food and Drug Administration (FDA) approved a de novo 510k classification (class II, special controls, product code: NCG) for the generic device: Neuropsychiatric Interpretive Electroencephalograph Assessment Aid. According to the FDA documentation, a Neuropsychiatric Interpretive Electroencephalograph Assessment Aid is a device prescribed by a physician that uses a patient's EEG 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 scatter plots.
- The device design must include safeguards to prevent use of the device 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 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

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.

CPT Codes:

95700-95726	Electroencephalogram (EEG) monitoring code range
95812-95819	Electroencephalogram (EEG) monitoring code range
95957	Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)

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POLICY HISTORY:

Adopted for Blue Advantage, October 2014
Available for comment October 21 through December 4, 2014
Medical Policy Group, October 2015
Medical Policy Group, October 2017
Medical Policy Group, November 2018 **(3)**: Updates to Key Points, and References. No changes to policy statement or intent.
Medical Policy Group, November 2019
Medical Policy Group, December 2019: Annual Coding Update
Medical Policy Group, November 2020
Medical Policy Group, October 2021
Medical Policy Group, October 2022
Medical Policy Group, October 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.
