MEDICAL POLICY

POLICY TITLE	QUANTITATIVE ELECTROENCEPHALOGRAPHY AS A DIAGNOSTIC AID FOR ATTENTION DEFICIT/HYPERACTIVITY DISORDER
POLICY NUMBER	MP 2.095

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2024**

I. POLICY

Quantitative electroencephalographic-based assessment of the theta/beta ratio is considered **investigational** as a diagnostic aid for attention deficit/hyperactivity disorder. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 2.064 Biofeedback and Neurofeedback Therapy
MP 2.304 Autism Spectrum Disorders

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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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 2 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 (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 a substantial amount of research 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 is 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 electroencephalography (QEEG) system 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. 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 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 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 MP 2.064). This treatment employs principles of biofeedback using EEG brain wave activity and attempts to alter the brain wave patterns in beneficial ways.

REGULATORY STATUS

In 2011, the generic device Neuropsychiatric Interpretive Electroencephalograph Assessment Aid was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA; class II, special controls, product code: NCG). According to FDA documentation, a neuropsychiatric interpretive electroencephalograph 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 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. FDA product code: NCG

IV. RATIONALE

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Summary of Evidence

For individuals who are suspected of having ADHD who received quantitative electroencephalography, the evidence includes a number of studies on brain wave patterns, particularly the theta/beta ratio. Relevant outcomes are test accuracy, symptoms, functional outcomes, and medication use. Numerous studies have evaluated brain wave patterns with standard electroencephalography equipment, and a pivotal trial, submitted to the U.S. Food and Drug Administration, measured the theta/beta ratio with the NEBA system. In the pivotal trial, both the specificity and positive predictive value of quantitative electroencephalography were

high. The reclassification analysis suggests that a negative NEBA 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 the effects of the technology on health outcomes.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Quantitative electroencephalography as diagnostic aid for ADHD is investigational; therefore, not covered:

Procedure Codes								
95812	95813	95816	95819	95957	S8040			

IX. REFERENCES

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1. *Adamou M, Fullen T, Jones SL. EEG for Diagnosis of Adult ADHD: A Systematic Review With Narrative Analysis. Front Psychiatry. 2020; 11: 871. PMID 33192633*
2. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder. TEC Assessments. 2014;Volume 29:Tab 1.*
3. *Food and Drug Administration. De novo classification request for Neuropsychiatric EEG-Based Assessment Aid for ADHD (NEBA) System (K112711). 2013*
4. *Snyder SM, Rugino TA, Hornig M, et al. Integration of an EEG biomarker with a clinician's ADHD evaluation. Brain Behav. Apr 2015; 5(4): e00330. PMID 25798338*
5. *Snyder SM, Quintana H, Sexson SB, et al. Blinded, multi-center validation of EEG and rating scales in identifying ADHD within a clinical sample. Psychiatry Res. Jun 30 2008; 159(3): 346-58. PMID 18423617*
6. *van Dijk H, deBeus R, Kerson C, et al. Different Spectral Analysis Methods for the Theta/Beta Ratio Calculate Different Ratios But Do Not Distinguish ADHD from Controls. Appl Psychophysiol Biofeedback. Sep 2020; 45(3): 165-173. PMID 32436141*
7. *Wolraich ML, Hagan JF, Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. Oct 2019; 144(4). PMID 31570648*
8. *Gloss D, Varma JK, Pringsheim T, et al. Practice advisory: The utility of EEG theta/beta power ratio in ADHD diagnosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. Nov 29 2016; 87(22): 2375-2379. PMID 27760867*
9. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 3.01.03, Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder. November 2023*

X. POLICY HISTORY

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MP 2.095	**CAC 1/28/14** New policy. BCBSA adopted. Procedure is considered investigational as a diagnostic aid for neuropsychiatric disorders, including but not limited to Attention Deficit/hyperactivity disorder.
	CAC 1/27/15 Consensus. Wording of policy statement changed to clarify the type of quantitative EEG and the diseases addressed in the policy; intent of the policy statement unchanged. References and rationale updated. Codes reviewed.

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	CAC 1/26/16 Consensus. No change to policy statements. References and rationale updated. Coding reviewed.
	Administrative Update 11/10/16 Variation reformatting
	CAC 7/25/17 Consensus. Policy statement unchanged. Cross-Reference, Rationale and Reference sections updated. Coding reviewed.
	5/16/18 Consensus review. Policy statement unchanged. Cross-Reference, Description/Background, Rationale and Reference sections updated.
	3/29/19 Consensus Review. Policy statement unchanged. References updated.
	3/17/20 Consensus Review. Policy Statement unchanged. References updated. Coding reviewed.
	11/24/2021 Consensus review. Updated cross-references, FEP, regulatory status, and references.
	12/30/2022: Consensus review. Updated background, coding table, and references.
	12/29/2023: Consensus review. Updated references. No changes to coding.

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