

Corporate Medical Policy

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

File Name: quantitative_electroencephalography_as_a_diagnostic_aid_for_adhd
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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. 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.

Background

Attention-deficit/hyperactivity disorder 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.

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 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 NEBA® system is a specific 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. 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

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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, 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 brain wave patterns in beneficial ways.

Regulatory Status

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 (cut-offs).
- 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 (PPV) and negative predictive value (NPV) 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.

The Neuropsychiatric EEG-based Assessment Aid (NEBA®; Lexicor Medical Technology, LLC, Augusta, GA) for ADHD was cleared for marketing in 2013 as a de novo device indicated to measure the theta/beta ratio of the EEG at electrode CZ on patients 6-17 years of age, combined with a clinician's evaluation, to aid in the diagnosis of ADHD (K112711). 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 a clinical evaluation. The device is not intended to be used as a stand-alone in the evaluation or diagnosis of ADHD.

The Lexicor QEEG system is marketed as a diagnostic aid for ADHD. Lexicor Medical Technology provides an internet analysis service of the QEEG, producing a DataLex report. Lexicor Medical Technology also developed the NEBA system.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Quantitative electroencephalographic (EEG)-based assessment of the theta/beta ratio is considered investigational as a diagnostic aid for attention deficit/hyperactivity disorder. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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

Not applicable.

When Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder is not covered

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

Policy Guidelines

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 symptoms, functional outcomes, and medication use. Numerous studies have evaluated brain wave patterns with standard electroencephalography equipment, and a pivotal trial, submitted to 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 electroencephalography 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 the effects of the technology on health outcomes.

The American Academy of Neurology (2016) 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."

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

This testing would likely be reported with existing electroencephalography codes (95812, 95813, 95816, 95819) and 95957 would be reported for the analysis.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

Boutros N, Fraenkel L, Feingold A. A four-step approach for developing diagnostic tests in psychiatry: EEG in ADHD as a test case. *J Neuropsychiatry Clin Neurosci* 2005; 17(4):455-64.

Subcommittee on Attention-Deficit/Hyperactivity Disorder Steering Committee on Quality Improvement Management, Wolraich M, Brown L et al. ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. *Pediatrics* 2011; 128(5):1007-22.

U.S. Food and Drug Administration. De novo classification request for Neuropsychiatric EEG-Based Assessment Aid for ADHD (NEBA) System. 2013. Available online at: http://www.accessdata.fda.gov/cdrh_docs/reviews/K112711.pdf. Last accessed January, 2014.

BCBSA Medical Policy Reference Manual [Electronic Version]. 3.01.03, 10/10/13

Specialty Matched Consultant Advisory Panel – 7/2014

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BCBSA Medical Policy Reference Manual [Electronic Version]. 3.01.03, 10/15/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 3.01.03, 10/12/2017

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 3.01.03, 10/10/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 3.01.03, 10/17/2019

Specialty Matched Consultant Advisory Panel – 6/2020

Policy Implementation/Update Information

1/28/14 New policy developed. Quantitative electroencephalographic (EEG)-based assessment is considered investigational as a diagnostic aid for neuropsychiatric disorders. Medical Director review 1/2014. (sk)

8/12/14 Specialty Matched Consultant Advisory Panel review 7/29/14. No change to Policy statement. (sk)

2/24/15 Reference added. Policy statement changed from “Quantitative electroencephalographic (EEG)-based assessment is considered investigational as a diagnostic aid for neuropsychiatric disorders” to “Quantitative electroencephalographic (EEG)-based assessment of the theta/beta ratio is considered investigational as a diagnostic aid for attention deficit/hyperactivity disorder”. Policy non coverage statement changed from

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“Quantitative electroencephalographic (EEG)-based assessment that reports the strength, pattern and/or ratios of brain waves is considered investigational as a diagnostic aid for neuropsychiatric disorders, including but not limited to attention-deficit/hyperactivity disorder” to “Quantitative electroencephalographic (EEG)-based assessment of the theta:beta ratio is considered investigational as a diagnostic aid for attention-deficit/hyperactivity disorder”. Intent of the Policy statement unchanged. (sk)

- 9/1/15 Specialty Matched Consultant Advisory Panel review 7/29/15. (sk)
- 12/30/15 Reference added. Codes 95816 and 95819 added to Billing/Coding section. Policy Guidelines updated. (sk)
- 8/30/16 Specialty Matched Consultant Advisory Panel review 7/27/2016. Policy statement unchanged. (an)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (an)
- 7/27/18 Reference added. Specialty Matched Consultant Advisory Panel review 6/27/2018. No change to policy statement. (an)
- 7/30/19 Updated Description section and Policy Guidelines. References added. Specialty Matched Consultant Advisory Panel review 7/10/2019. (eel)
- 7/28/20 Removed Biofeedback policy reference from Background and Related Policies sections. References added. Specialty Matched Consultant Advisory Panel review 6/2020. No change to policy statement. (bb)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.