

**SUBJECT:** NEUROPSYCHIATRIC QUANTITATIVE ENCEPHALOGRAPHY IN THE DIAGNOSIS OF ATTENTION DEFICIT/HYPERACTIVITY DISORDER

**POLICY NUMBER:** 3.01.12

**CATEGORY:** Technology Assessment

**EFFECTIVE DATE:** 05/22/14

**PAGE:** 1 OF: 4

- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

## **POLICY STATEMENT:**

Based upon our criteria and assessment of peer-reviewed literature, quantitative electroencephalographic (EEG)-based assessment that reports the strength, pattern and/or ratios of brain waves has not been medically proven to be effective and is considered **investigational** as a diagnostic aid for neuropsychiatric disorders, including but not limited to attention-deficit/hyperactivity disorder.

*Refer to Corporate Medical Policy # 2.01.22 regarding Topographic Brain Mapping*

## **POLICY GUIDELINES:**

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## **DESCRIPTION:**

Attention-deficit/hyperactivity disorder is a common disorder in children, adolescents, and adults. ADHD is defined as involving pervasive symptoms of inattention and/or hyperactivity-impulsivity. 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 be a result of environmental influences such as a lack of discipline.

Patients with attention-deficit/hyperactivity disorder (ADHD) may have alterations in their brain wave patterns that can be measured by quantitative electroencephalography (EEG). EEG is typically categorized into 4 frequency ranges, delta (less than 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 quantitative EEG system (QEEG) that measures the resting theta/beta ratio of the EEG with an electrode located at the central midline position (CZ). 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.

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.

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**RATIONALE:**

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.

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.

The Neuropsychiatric EEG-based Assessment Aid (NEBA®) 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.

There are no published peer-reviewed studies that evaluate the accuracy of the commercially available device (NEBA) in the diagnosis of ADHD. The currently available evidence consists of studies that report quantitative EEG (QEEG) results using standard EEG equipment and results of the pivotal FDA studies that led to approval of the NEBA system. Data submitted to the FDA included test-retest reliability of the NEBA theta/beta ratio for EEG data from 198 patients who had recordings on 2 different days (about 2 ½ weeks apart on average). The intraclass correlation coefficient of repeated NEBA theta/beta ratio was 0.83, which is considered to be high. In the published studies, there were no reports identified that measured the reliability of QEEG. Data submitted to the FDA regarding diagnostic accuracy were from a multicenter study of 275 children and adolescents (6-18 years) who presented with attention and/or behavioral concerns to one of 13 clinics in the U.S. Diagnostic evaluation for ADHD and other disorders was conducted with clinical interview and rating scales that included behavior rating scales, IQ and achievement testing, and scales of severity and dysfunction. A consensus best-estimated 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 de-identified patient files, but did not conduct an interview or have access to the parent rating scales, features which are considered critical for a gold standard diagnosis of ADHD. A separate group of investigators who were unaware of the clinical diagnosis collected the EEG data (NEBA system). When compared to the consensus diagnosis, NEBA was found to have a sensitivity of 89%, specificity of 87%, positive predictive value (PPV) of 81% and negative predictive value (NPV) of 93% for adolescents (12-17 years). For children (6-11 years), NEBA had sensitivity of 79%, specificity of 97%, PPV of 96% and NPV of 82%.

Current evidence includes numerous studies that have evaluated quantitative EEG at CZ with standard EEG equipment, and one pivotal trial submitted to the U.S. Food and Drug Administration (FDA) that used the NEBA system to assess test-retest reliability, sensitivity, specificity, and reclassification analysis in an appropriate population of patients. In the FDA pivotal trial, the specificity and positive predictive value of QEEG was high, although the reclassification analysis showed little benefit of a positive NEBA over clinical assessment alone. 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. Further research is needed to evaluate the potential impact of NEBA on management of ADHD. In addition, the effect of the test on patient outcomes, such as rates of medication use, would allow greater certainty regarding the usefulness of NEBA.

The larger body of evidence also raises questions about the utility of measuring the theta/beta ratio in patients suspected of ADHD, as this has not been a consistent finding across studies. Recent studies show low accuracy (58%) and no significant increase in the theta/beta ratio in children and adolescents with ADHD compared to age- and sex-matched controls. Other studies show an increase in beta (rather than a decrease) in a subgroup of affected children and adolescents. Additional studies are needed to determine how strongly the theta/beta ratio is associated with ADHD.

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<b>POLICY NUMBER: 3.01.12</b>	
<b>CATEGORY: Technology Assessment</b>	<b>PAGE: 3 OF: 4</b>

**CODES:**      Number      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

There are no specific CPT codes for neuropsychiatric QEEG; however, it would likely be reported with existing electroencephalography CPT codes.

<b>CPT:</b>	95812-95819	Electroencephalogram (EEG) monitoring (code range)
	95957	Digital analysis of electroencephalogram (EEG)

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**HCPCS:** There are no specific codes

**ICD9:** Investigational for all diagnoses

**ICD10:**      Investigational for all diagnoses

## **REFERENCES:**

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**KEY WORDS:**

ADD, ADHD, NEBA System, Quantitative EEG

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## **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

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Based upon our review, neuropsychiatric quantitative EEG is not addressed in National or regional CMS coverage determinations or policies.