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

Policy # 00444
Original Effective Date: 12/16/2015
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When Services Are Considered Investigational
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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.*

Background/Overview
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 2 domains of the work, school, or home environments. Stimulant medications reduce symptoms associated with ADHD, although there are concerns about the potential for overdiagnosis 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.

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 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

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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. 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.

**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 by the FDA (class II, special controls, product code: NCG). 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 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; Lexicor Medical Technology, Augusta, GA) for ADHD was granted a de novo 510(k) classification by FDA. The device is indicated to measure the theta/beta ratio of the EEG at electrode CZ on patients 6 to 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. FDA Product Code: NCG.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Rationale/Source**
Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

**QUANTITATIVE ELECTROENCEPHALOGRAPHY**

**Clinical Context and Test Purpose**
The purpose of quantitative electroencephalography (QEEG) in patients who are suspected of having attention-deficit/hyperactivity disorder (ADHD) is to inform a decision whether to initiate specific therapy.

The question addressed in this evidence review is: Does the use of QEEG improve the net health outcome in individuals suspected of having ADHD?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is individuals with suspected ADHD.

**Interventions**
The test being considered is QEEG, using the Neuropsychiatric EEG-based ADHD Assessment Aid (NEBA) system, as part of a clinical evaluation.
Comparators
The following practice is currently being used to diagnose ADHD: clinical evaluation alone.

Outcomes
The general outcomes of interest are patient symptoms, functional outcomes, and medication use.

Timing
QEEG testing and analysis is conducted as part of a clinical evaluation.

Setting
Quantitative electroencephalography would be administered in an outpatient setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

A number of studies have measured theta activity or the theta/beta ratio in children and adolescents with ADHD compared with nonaffected controls. The most commonly reported alteration in EEG is an increase in the theta/beta ratio. However, some studies have reported that other patterns (e.g., increased beta wave activity) are found in some patients, and several recent studies have found no significant difference in theta activity in a clinical vs nonclinical population.

Systematic Reviews
A TEC Assessment (2014) evaluated the evidence related to the use of QEEG with the NEBA system in the diagnosis of ADHD. This evidence considered was submitted to the U.S. Food and Drug Administration (FDA) in 2013 and subsequently published by Snyder et al (2015). The evidence on the accuracy of NEBA in the diagnosis of ADHD consisted of data submitted to FDA from 275 children and adolescents (6-18 years) who presented with attention and/or behavioral concerns to one of 13 clinics in the United States. The evidence also included a discussion of the technical performance of NEBA for the diagnosis of ADHD included test-retest reliability of the NEBA theta/beta ratio for EEG data from 198 patients who had recordings on 2 different days. Evidence of the technical performance is beyond the scope of this evidence review. No studies were identified that assessed whether the reclassification of patients suspected of having ADHD, as reported to FDA, improved health outcomes.
Previously, a systematic review by Snyder and Hall (2006) included 9 studies (total N=1498 patients) that used Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria and screening tests in a clinical setting. The meta-analysis identified a mean increase of theta power of 32% and a pooled effect size of 3.08 for the theta/beta ratio in patients who had ADHD compared with unaffected children, adolescents, and adults. It was noted that the included studies often had retrospectively defined limits and that an increase in the theta/beta ratio has also been identified in other conditions.

A systematic review by Boutros et al (2005) included 17 studies evaluating theta activity in children and adolescents with ADHD. The meta-analysis found a weighted mean effect size of 0.59 for an absolute increase in theta activity and a mean effect size of 0.91 for theta relative to total EEG activity.

Nonrandomized Studies
Other studies have found no significant difference in theta activity in a clinical population with ADHD. Liechti et al (2013) compared the theta/beta ratio in 32 children and 22 adults with ADHD vs healthy controls who were matched for age, sex, and IQ. Resting EEG was measured separately for the 3 midline electrodes (frontal [FZ], central [CZ], parietal [PZ]) and for frontal, central, and parietal regions. The study found a decrease in theta activity with age, but no consistent increase in theta or theta/beta ratio in patients with ADHD compared with controls. There was no evidence for a maturational lag in patients with ADHD. Ogrim et al (2012) assessed differences in theta activity measured at CZ in 62 children and adolescents with a tentative diagnosis of ADHD compared with 39 sex- and age-matched controls. The overall accuracy at CZ was 63% for theta and 58% for the theta/beta ratio compared with nonaffected controls. Elevations of theta were found in 25.8% of patients compared with 2.6% of controls. None of the EEG measures were statistically significant for discerning patients from controls. In other studies, subgroups of children with ADHD have been shown to have increased beta activity instead of decreased beta or increased theta/beta ratio. In a study of QEEG in combination with the Connors’ Continuous Performance Test and the Test of Variables of Attention in the diagnosis of ADHD in 157 children, 85 with and 72 without ADHD based on Diagnostic Interview Schedule for Children (Version IV), Kim et al (2015) reported that the ADHD group had significantly higher theta wave values in 13 positions, while for the theta/beta ratio, the ADHD group had higher values for only 1 position (right frontal lobe).

Diagnostic Accuracy Studies of the Theta/Beta Ratio
Data submitted to FDA regarding the diagnostic accuracy of the NEBA system were from the multicenter study of 275 children and adolescents (6-18 years, described above) who presented with attention and/or behavioral concerns to one of 13 clinics in the United States. An additional 89 children and adolescents were recruited but did not complete the study, and, of these, 67 had incomplete EEG recordings. Diagnostic evaluation for ADHD and other disorders was conducted with a clinical interview and rating scales that included behavior rating scales, IQ and achievement testing, and scales of severity and dysfunction. A consensus best-estimate 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 deidentified patient files; however, they did not interview patients or have access to the...
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Snyder et al (2008) also reported on the accuracy of the theta/beta ratio for the diagnosis of ADHD in an industry-sponsored, investigator-blinded, multicenter study. Patients (N=159) ages 6 to 18 who had presented to 1 of 4 psychiatric and pediatric clinics with suspected attention and behavioral symptoms were evaluated in a standardized semi-structured manner according to DSM-IV criteria by a clinical team trained on the study instruments. Rating scales were distributed to parents and teachers and held in sealed envelopes until the blind was broken. EEG was collected separately by investigators, blinded to the clinical diagnosis, using a 19-electrode cap according to the 10-20 system with eyes open and eyes shut. A threshold of 1.5 standard deviation of the theta/beta ratio from normative database values (according to age) at electrode CZ was used to determine ADHD vs non-ADHD. With a prevalence of ADHD of 61% based on clinical diagnosis, the theta/beta ratio had a sensitivity of 87%, specificity of 94%, positive predictive value of 95%, and negative predictive value of 82%. The rating scales provided a sensitivity of 38% to 79% and specificity of 13% to 61%. Results from this study were used to set a new theta/beta threshold for analysis of data from the FDA-regulated study of the NEBA device.

Other studies have reported the lower accuracy of QEEG in the diagnosis of ADHD. In the Kim study (2015) previously reported, on receiver operating curve analysis, QEEG theta wave amplitude showed low accuracy for the diagnosis of ADHD (56.4%), and the theta/beta wave amplitude did not significantly predict ADHD diagnosis. Sangal et al (2015) evaluated the discriminatory power of QEEG measurements during auditory and visual tasks requiring selective attention in 28 control children and 58 children with ADHD. Subjects with ADHD had significantly higher average theta/beta ratios (2.6 vs 2.25; p=0.007) and lower average beta-I amplitudes (3.66 vs 4.22, p=0.01). The average theta/beta ratio had a sensitivity and specificity in diagnosing ADHD of 69% and 50%, respectively, while the theta/beta ratio at the CZ position had a sensitivity and specificity of 69% and 43%, respectively.

Section Summary: Clinically Valid
Patients who have ADHD may have altered brain wave patterns on QEEG compared with patients who do not. While an increased theta/beta ratio is the most common alteration reported, not all studies have found
this association, and some have reported other brainwave patterns in ADHD patients. A few studies have reported on the sensitivity and specificity of QEEG compared with clinical diagnosis. In these studies, sensitivity ranged from 69% to 89% and specificity from 43% to 97%. However, a weakness of these studies is the lack of a true criterion standard for the diagnosis of ADHD.

**Clinically Useful**
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

**Direct Evidence**
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

A proposed benefit of the NEBA system is a reduction in the overdiagnosis of ADHD, thereby lessening the risks of unnecessary pharmacologic therapy in children and adolescents. There were no published studies that directly reported on clinical outcomes, such as measures of disease activity and/or medication use.

**Chain of Evidence**
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

The pivotal FDA study reported on the reclassification of diagnosis following NEBA; this may be considered an indirect measure that may impact outcomes.

The evidence related to whether QEEG improves the clinical diagnosis of patients with suspected ADHD consists of the material submitted to FDA as part of the NEBA's approval process, as previously described. The study included reclassification tables to demonstrate whether NEBA provides additional information beyond the clinician's initial diagnosis, which are summarized in Table 1. Use of NEBA was consistent with the categorization of patients diagnosed with ADHD by both the initial clinical diagnosis and the consensus diagnosis. For example, 95 (73%) of 130 children and adolescents who were considered to have ADHD by the consensus diagnosis were classified as ADHD by both the clinician alone and NEBA. Reclassification was observed when using NEBA for patients diagnosed by clinician alone as ADHD and consensus as non-ADHD. For example, 145 children and adolescents had a non-ADHD diagnosis by the consensus. Of the 145, 93 had received an initial clinical diagnosis of ADHD, but 85 (91%) were negative by NEBA.

<table>
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<th>Consensus Diagnosis</th>
<th>Initial Clinical Diagnosis</th>
<th>Total</th>
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<tr>
<td>ADHD</td>
<td>NEBA interpretation</td>
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<tr>
<td></td>
<td>+</td>
<td>95 (81.9)</td>
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<tr>
<td></td>
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<td>11 (78.6)</td>
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<table>
<thead>
<tr>
<th></th>
<th>+</th>
<th>-</th>
<th>Total</th>
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<tbody>
<tr>
<td>Not ADHD</td>
<td>21</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>NEBA interpretation(^a)</td>
<td>8</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>85</td>
<td>51</td>
<td>136</td>
</tr>
<tr>
<td>Total</td>
<td>93</td>
<td>52</td>
<td>145</td>
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</table>

ADHD: attention-deficit hyperactivity disorder; FDA: Food and Drug Administration; NEBA: Neuropsychiatric EEG-Based Assessment Aid; NEBA interpretation: NEBA results plus initial clinical diagnosis.

\(^a\) The consensus diagnosis is assumed to be the reference standard (ie, correct). Two categories are included in the ADHD consensus diagnosis: diagnosed with ADHD or referred for more testing for the condition. Similarly, the “not ADHD” diagnosis included those diagnosed as not having ADHD or as needing more testing for other conditions.

\(^b\) The NEBA interpretation is a composite of both the initial clinical diagnosis and the NEBA results, like a dichotomized posttest probability. The performance measures are presumably calculated assuming that a negative NEBA result can override a positive initial clinical diagnosis, but in the FDA summary, it was stated that a negative diagnosis can only result from a negative initial clinical diagnosis (ie, the NEBA interpretation cannot override it).

Section Summary: Clinically Useful

Reclassification results from the pivotal trial suggest that NEBA may support an alternative diagnosis in patients initially suspected of having ADHD but not confirmed by consensus diagnosis. No studies were identified that addressed whether clinical outcomes were improved for patients with suspected ADHD who were reclassified by NEBA.

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 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.
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References

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

Policy History

Original Effective Date: 12/16/2015
Current Effective Date: 12/19/2018
12/03/2015 Medical Policy Committee review
12/16/2015 Medical Policy Implementation Committee approval. New Policy.
12/01/2016 Medical Policy Committee review
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017 Medical Policy Committee review

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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.
Next Scheduled Review Date: 12/2019

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