

Subject: Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder with the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System		Original Effective Date: 8/13/14
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SUMMARY ^{2 12 17 19}

The Neuropsychiatric EEG-Based 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). 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. Prescribed by a physician, the NEBA test takes approximately 20 minutes to perform with the individual resting quietly while wearing a cap containing electrodes that are affixed to the scalp. A compact EEG system records electrical impulses from the electrodes and measures the ratio between theta and beta brain wave frequencies. Proprietary software is used to analyze the data and generate the NEBA test report. The Food and Drug Administration (FDA) approved the NEBA system on July 15, 2013 as an aid for diagnosing ADHD in patients aged 6 to 17 years in conjunction with evaluation by a qualified clinician. According to the FDA, 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 and is NOT to be used as a stand-alone in the evaluation or diagnosis of ADHD.²

Attention-deficit/hyperactivity disorder is a common disorder in children, adolescents, and adults and defined as a syndrome with two categories of core symptoms: hyperactivity/impulsivity and inattention. The American Psychiatric Association has defined consensus criteria for the diagnosis of attention deficit disorder (ADHD), which are published in the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5). For children <17 years, the DSM-5 diagnosis of ADHD requires ≥6 symptoms of hyperactivity and impulsivity or

≥6 symptoms of inattention. For adolescent's ≥17 years and adults, ≥5 symptoms of hyperactivity and impulsivity or ≥5 symptoms of inattention are required. A diagnosis of ADHD requires a comprehensive evaluation that includes review of the medical, social, and family histories; clinical interviews with the parent and patient; review of information about functioning in school or day care; and evaluation for coexisting emotional or behavioral disorders. The necessary information may be obtained by face to face discussions and questionnaires.^{12 17 19}

Recommendation³⁻¹⁶

The Neuropsychiatric EEG-Based Assessment Aid (NEBA) System is considered investigational and unproven for the diagnostic workup of Attention-deficit/hyperactivity disorder (ADHD) because the peer reviewed medical evidence is insufficient to determine safety, efficacy and benefit on net health outcomes.

SUMMARY OF MEDICAL EVIDENCE³⁻¹¹

There are no published peer-reviewed studies that evaluate the accuracy of the 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. Other studies have reported lower accuracy of QEEG in the diagnosis of ADHD.² In the Kim et al. study (2015), QEEG theta wave amplitude showed low accuracy for the diagnosis of ADHD (56.4%), and theta/beta wave amplitude did not significantly predict ADHD diagnosis.⁸ 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 sensitivity and specificity in diagnosing ADHD of 69% and 50%, respectively, while the theta/beta ratio at the CZ position had sensitivity and specificity of 69% and 43%, respectively.¹⁰

Snyder et al. (2008) reported on 159 patients aged 6 to 18 years with suspected ADHD. Participating males (101) and females (58) aged 6 to 18 had presented to one of four psychiatric and pediatric clinics because of the suspected presence of attention and behavior problems. DSM-IV diagnosis was performed by clinicians assisted with a semi-structured clinical interview. EEG (theta/beta ratio) and ratings scales (Conners Rating Scales-Revised and ADHD Rating Scales-IV) were collected separately in a blinded protocol. ADHD prevalence in the clinical sample was 61%, whereas the remainder had other childhood/adolescent disorders or no diagnosis. Comorbidities were observed in 66% of ADHD patients and included mood, anxiety, disruptive, and learning disorders at rates similar to previous findings. EEG identified ADHD with 87% sensitivity and 94% specificity. Rating scales provided sensitivity of 38-79% and specificity of 13-61%. While parent or teacher identification of ADHD by rating scales was reduced in accuracy when applied to a diverse clinical sample, theta/beta ratio changes remained consistent with the clinician's ADHD diagnosis. The review concluded that because theta/beta ratio changes do not identify comorbidities or alternative diagnoses, the results do not support the use of EEG as a stand-alone diagnostic and should be limited to the interpretation that EEG may complement a clinical evaluation for ADHD.³

Quintana et al. (2007) reported on a smaller subset of this patient group to investigate the effectiveness of rating scales and electroencephalography (EEG) in detecting the presence of attention-deficit/hyperactivity disorder

(ADHD) within a diverse clinical sample. A standard psychiatric evaluation was used to assess 26 children/adolescents who presented to a clinic because a parent suspected the presence of ADHD. EEG data was collected in a blinded protocol, and rating scales were collected as well. Although all subjects had presented with ADHD-like symptoms, only 62% were diagnosed with ADHD, while the remaining 38% had other disorders or no diagnosis. Rating scales readily classified inattentive, impulsive, and/or hyperactive symptoms as being due to ADHD, regardless of the actual underlying disorder, leading to a sensitivity of 81% and a specificity of 22%. Previous studies have observed that there is an EEG marker that identifies ADHD vs. controls, and this marker was present in 15 out of 16 of the ADHD subjects (sensitivity=94%) and in none of the subjects with ADHD-like symptoms due to other disorders (specificity=100%). In the detection of ADHD in a diverse clinical sample, rating scales and EEG were both sensitive markers, whereas only EEG was specific. These results may have important implications to ADHD differential diagnosis. ⁴

Arns et al. (2013) conducted a meta-analysis on the theta/beta ratio (TBR) research in ADHD. Nine studies were identified with a total of 1253 children/adolescents with and 517 without ADHD. The grand-mean effect size (ES) for the 6-13 year-olds was 0.75 and for the 6-18 year-olds was 0.62. However the test for heterogeneity remained significant; therefore these ESs are misleading and considered an overestimation. Post-hoc analysis found a decreasing difference in TBR across years, explained by an increasing TBR for the non-ADHD groups. The review concluded that excessive TBR cannot be considered a reliable diagnostic measure of ADHD, however a substantial sub-group of ADHD patients do deviate on this measure and TBR has prognostic value in this sub-group, warranting its use as a prognostic measure rather than a diagnostic measure. ⁵

Professional Society Guidelines ¹²⁻¹⁶

The American Academy of Neurology Practice Advisory (2016) states that “It is unknown whether a combination of standard clinical examination and EEG theta/beta power ratio increases diagnostic certainty of ADHD compared with clinical examination alone.” ¹⁴

A Blue Cross and Blue Shield Association (BCBSA) TEC Assessment report (2014) evaluated the evidence related to the use of quantitative EEG in the diagnosis of ADHD and concluded that no published peer-reviewed studies evaluated the accuracy of the NEBA System in the diagnosis of ADHD and that the studies have not determined whether the NEBA System improves diagnostic accuracy of ADHD and health outcomes. ¹⁵

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
95961	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by a physician or other qualified health care professional.
95962	each additional hour of attendance by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
95812-95830	Electroencephalography
HCPCS	Description
	N/A
ICD-10	Description: [For dates of service on or after 10/01/2015]

F90.0	Attention-deficit hyperactivity disorder, predominantly inattentive type
F90.1	Attention-deficit hyperactivity disorder, predominantly hyperactive type
F90.2	Attention-deficit hyperactivity disorder, combined type
F90.9	Attention-deficit hyperactivity disorder, unspecified type

RESOURCE REFERENCES

Government Agency

- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. Advanced Search: National Coverage Documents [search:]. Available at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>.
- 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.

Peer Reviewed Publications

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- Arns M, Conners CK, Kraemer HC. A decade of EEG Theta/Beta Ratio Research in ADHD: a meta-analysis. *J Atten Disord.* 2013 Jul;17(5):374-83. Epub 2012 Oct 19.
- Liechti MD, Valko L, Muller UC, et al. Diagnostic value of resting electroencephalogram in attentiondeficit/hyperactivity disorder across the lifespan. *Brain Topogr.* Jan 2013;26(1):135-151. PMID 23053601
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- Sangal RB, et al. Use of EEG beta-1 power and theta/beta ratio over Broca's area to confirm diagnosis of attention deficit/hyperactivity disorder in children. *Clin EEG Neurosci* 2015 Jul;46(3):177-82.
- 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

Professional Society Guidelines

12. National Institute of Mental Health (NIMH). What is Attention Deficit Hyperactivity Disorder (ADHD, ADD)? Accessed at: <http://www.nimh.nih.gov/health/topics/attention-deficit-hyperactivity-disorder-adhd/index.shtml>
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14. American Academy of Neurology: 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 November 29, 2016 vol. 87 no. 22 2375-2379. Accessed at: <http://www.neurology.org/content/87/22/2375.short?sid=a325aa8f-cbd7-4883-838c-efd4bd3b5562>
15. BlueCross BlueShield Association Technology Evaluation Center (TEC). Quantitative electroencephalography as a diagnostic aid for Attention-Deficit/Hyperactivity Disorder. 2014 Oct (29).
16. American Academy of Pediatrics (AAP) Attention-deficit, subcommittee on ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents." Pediatrics (2011): peds-2011.

Other Resources

17. UpToDate: [website]. Waltham, MA: Walters Kluwer Health; 2019. Krull K, et al. Attention deficit hyperactivity disorder in children and adolescents: clinical features and diagnosis.
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Review/Revision History:

8/13/14: Policy created

12/16/15, 6/15/16: Policy reviewed, no changes.

9/7/17: The policy was reviewed and the clinical criteria has not changed. MCP name changed from Neuropsychiatric EEG-Based Assessment Aid (NEBA) System to QEEG as above. The following sections were updated: summary of medical evidence, professional guidelines and references.

7/10/18 & 6/19/19: Policy reviewed, no changes to criteria. Updated coding tables.