![Molina Healthcare logo]

| Subject: Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder with the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System | Original Effective Date: 8/13/2014 |
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| **Policy Number:** MCP-180 | **Revision Date(s):** 9/7/2017 |
| **Review Date:** 12/16/2015, 6/15/2016, 7/10/2018, 6/19/2019, 6/17/2020, 8/11/2021 | |
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# Contents

## DISCLAIMER

*This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]*

## DESCRIPTION [2-5]

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.[5]

## Position Statement

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 EVIDENCE [6-22]

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.[11] 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.[13]

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.[6]

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.[7]

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.[8]

## PROFESSIONAL STATEMENTS

The **American Academy of Neurology Practice Advisory** 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.[23]

The **American Academy of Pediatrics (AAP)** published the *Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents.* The 2019 guideline updates the 2011 version. In that time, the Diagnostic and Statistical Manual of Mental Disorders has been revised to the 5th edition and new ADHD-related research has been published. Results of the publications

do not support major changes to the previous AAP recommendations. Incremental updates made include the addition of a key action statement related to diagnosis and treatment of comorbid conditions in children and adolescents with ADHD. The accompanying process of care algorithm was been updated to assist in implementing the guideline recommendations. During the review process, numerous systemic barriers were identified that restrict and/or hamper pediatric clinicians' ability to adopt their recommendations. The subcommittee created a companion article (see *Supplemental Information* in the guideline) regarding systemic barriers to the care of children and adolescents with ADHD. The identification of major systemic-level barriers presents recommendations to address barriers.[24]

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.[25]

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 |
| --- | --- |
| 95812 | Electroencephalogram (EEG) extended monitoring; 41-60 minutes |
| 95813 | Electroencephalogram (EEG) extended monitoring; greater than 1 hour |
| 95816 | Electroencephalogram (EEG); including recording awake and drowsy |
| 95819 | Electroencephalogram (EEG); including recording awake and asleep |
| **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 Agencies**

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**Peer Reviewed Literature**

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23. 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 July 16, 2021.
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**Other Peer Reviewed and Professional Organization Publications (used in the development of this policy)**

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## REVIEW/REVISION HISTORY

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| **8/13/2014** | New policy. |
| **12/16/2015** | Policy reviewed, no changes. |
| **6/15/2016** | Policy reviewed, no changes. |
| **9/7/2017** | Policy reviewed; no changes. Title changed from *Neuropsychiatric EEG-Based Assessment Aid (NEBA) System*. Updated Summary of Medical Evidence section and references. |
| **7/10/2018** | Policy reviewed, no changes to criteria; updated coding tables. |
| **6/19/2019** | Policy reviewed, no changes to criteria; updated coding tables. |
| **6/17/2020** | Policy reviewed, no changes to criteria. |
| **6/8/2021** | Policy removed, no changed to criteria; updated coding tables (removed CPT codes 95961, 95962; added EEG only codes: 95812, 95813, 95816, 95819). |
| **8/11/2021** | Policy reviewed, no changes to criteria. No new peer reviewed literature found that would change our position, topic remains experimental. Updated references. |