Molina Clinical Policy Quantitative Electroencephalography as a Diagnostic Aid for ADHD with the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System: Policy No. 180



Last Approval: 8/10/2022 Next Review Due By: August 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

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 attention deficit/hyperactivity disorder (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. (FDA, 2011).

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 ADHD, which are published in the *Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5)*. For children over 17 years, the DSM-5 diagnosis of ADHD requires 6 or more symptoms of hyperactivity and impulsivity or ≥6 symptoms of inattention. For adolescents over 17 years and adults, 5 or more symptoms of hyperactivity and impulsivity or 5 or more 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. (Hayes, 2021; NIMH, 2021).

COVERAGE POLICY

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

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

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SUMMARY OF MEDICAL EVIDENCE

There are no published peer-reviewed studies that evaluate the accuracy of the NEBA device 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 (FDA, 2011). 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 (Kim et al., 2015).

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) and lower average beta-I amplitudes (3.66 vs 4.22). 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.

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. The prevalence of ADHD 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.

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 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 observed 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.

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 6- to 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.

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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 (Gloss et al., 2016).

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. (Wolraich et al., 2019).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

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 Codes – N/A

ICD-10 Codes

ICD-10	Description
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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/10/2022	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections.
8/11/2021	Policy reviewed, no changes to criteria, updated references. Literature review found no evidence to support a criteria change.
	Coding updated – removed CPT codes 95961, 95962; added EEG only codes: 95812, 95813, 95816, 95819).
6/17/2020	Policy reviewed, no changes to criteria.

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6/19/2019 Policy reviewed, no changes to criteria; updated coding tables. **7/10/2018** Policy reviewed, no changes to criteria; updated coding tables.

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.

6/15/2016 Policy reviewed, no changes. **12/16/2015** Policy reviewed, no changes.

8/13/2014 New policy.

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.