

# 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: 8/9/2023

Next Review Due By: August 2024



### 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 (Krull & Chan 2023). 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)* (Krull & Chan 2023). For children over 17 years, the DSM-5 diagnosis of ADHD requires 6 or more symptoms of hyperactivity and impulsivity or  $\geq 6$  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 2022).

### COVERAGE POLICY

The 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 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).

Ji et al. (2022) completed a study using QEEG to evaluate the characteristics of ADHD subtypes in children. The study included 69 participants between the ages of 7-12 years with a diagnosis of ADHD based on the DSM-5 criteria. In addition, an ADHD diagnosis had to be confirmed using the Kiddie Schedule for Affective Disorders and Schizophrenia–Present and Lifetime Korean version (K-SADS-PL-K) interview tool with a confirmation of ADHD by more than one doctor specializing in child and adolescent psychiatry. Those that did not meet the DSM-5 or K-SADS-PL-K criteria were placed into the neurotypical group. Of the 69 participants, 42 met criteria for inclusion in the ADHD group and 27 were included in the neurotypical group. Exclusion criteria included a history of brain damage, neurological or genetic disorders, substance dependence, epilepsy, any other mental disorder, and an intelligence quotient  $\leq 70$ . QEEG was analyzed using delta, theta, alpha 1, alpha 2, beta 1, beta 2, beta 3, and gamma frequency bands. Results showed three ADHD subtypes. The first subtype was characterized by “significant differences in alpha 2, beta 2, and beta 3 relative powers” in the temporal region. The second subtype was characterized by high absolute powers in the delta and theta bands in the cerebral regions and lower “relative powers of the beta 3 band in the occipital region and alpha 2 bands in the frontal region” in comparison to the neurotypical group. The third subtype was characterized by higher absolute and relative powers in the beta band in all regions. Researchers noted that electrophysiological heterogeneity must be taken into consideration when utilizing QEEG to diagnose ADHD. In addition, EEGs change as children age, and it may be misleading to only utilize an EEG from one specific time.

Byeon et al. (2020) completed a study to investigate QEEG subtypes as a means to diagnose ADHD. The study included 74 participants between the ages of 7-12 years. Participants had to be diagnosed with ADHD according to the DSM-5 criteria to be included in the study. Those with a history of brain damage, neurological and genetic disorders, substance dependency, epilepsy, or any other mental disorder were excluded from the study. Those with an intelligence quotient  $\leq 70$  were also excluded. ADHD behavior was assessed using the 18-item Korean version of the ADHD Rating Scale. EEG recordings were obtained in a dimly lit, electrically shielded, sound-attenuated room. Recordings were approximately 3 minutes in length and researchers selected at least 2 minutes of artifact-free readings from each recording. Delta, theta, slow alpha, fast alpha, and beta frequency bands were analyzed from the selected recordings. Absolute powers were averaged, and all data was converted to Z scores using the NeuroGuide normative database. Participants were categorized into three groups: ADHD (n=27), ADHD Not Otherwise Specified (n=32), and Neurotypical (n=15). All frequency bands were compared between all three groups and researchers found four QEEG clusters: 1) elevated delta power with lower theta activity, 2) elevated slow alpha relative power, 3) elevated theta with deficiencies in alpha and beta relative power, and 4) elevated fast alpha and beta absolute power. Those in the ADHD group were the largest proportion of clusters 1 and 3. Those in the ADHD Not Otherwise Specified group were the largest proportion of cluster 2. Those in the neurotypical group were the largest proportion of cluster 4.

McVoy et al. (2019) completed a systematic review to determine the feasibility of QEEG serving as a biomarker in childhood psychiatric disorders, including ADHD. A total of 33 studies between 1996 and 2017 were included in the review with a total of 2268 patients between the ages of 4-18 years. The most common finding between all studies that included ADHD was a higher theta/beta ratio (TBR) for those with ADHD when compared to those without ADHD. Researchers noted that further research is needed as it is uncertain if QEEG abnormalities serve as nonspecific markers of psychiatric illness.

Arns et al. (2013) conducted a meta-analysis on the 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

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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.

### National and Specialty Organizations

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 DSM-5 has been revised 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 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. 2020).

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).

## CODING & BILLING INFORMATION

### CPT (Current Procedural Terminology) Codes

CPT	Description
95812	Electroencephalogram (EEG) extended monitoring; 41-60 minutes
95813	Electroencephalogram (EEG) extended monitoring; 61-119 minutes
95816	Electroencephalogram (EEG); including recording awake and drowsy
95819	Electroencephalogram (EEG); including recording awake and asleep
95957	Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)

**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

8/9/2023	Policy reviewed, no changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and References sections. Added code 95957 and updated description for code 95813. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. Removed Supplemental Information section and ICD-10 codes. IRO Peer Review on July 3, 2023, by a practicing, board-certified physician with a specialty in Child/Adolescent Psychiatry.
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 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.
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 <i>Neuropsychiatric EEG-Based Assessment Aid (NEBA) System</i> . Updated Summary of Medical Evidence section and references.

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6/15/2016 Policy reviewed, no changes.

12/16/2015 Policy reviewed, no changes.

8/13/2014 New policy.

### REFERENCES

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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.