Policy Statement

I. Quantitative electroencephalographic-based assessment of the theta/beta ratio is considered investigational as a diagnostic aid for attention-deficit/hyperactivity disorder.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

This testing would likely be reported with existing electroencephalography CPT codes. The clinician would report the appropriate code for electroencephalography (e.g., 95812-95813) and the code for digital analysis of electroencephalogram (95957) would be reported for the analysis.

Description

Patients with attention-deficit/hyperactivity disorder (ADHD) may have alterations in their brain wave patterns that can be measured by quantitative electroencephalography (EEG). A commercially available system, the Neuropsychiatric EEG-based ADHD Assessment Aid, measures the resting theta/beta ratio of the electroencephalogram. This technology is being evaluated to aid in the diagnosis of ADHD in adolescents and children for whom there is a clinical suspicion of ADHD.

Related Policies

- Neurofeedback

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2011, the generic device Neuropsychiatric Interpretive Electroencephalograph Assessment Aid was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA; class II, special controls, product code: NCG). According to the FDA documentation, a neuropsychiatric interpretive EEG assessment aid is a device prescribed by a physician that uses a patient’s electroencephalogram 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 device use 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; NEBA Health previously Lexicor Medical Technology) for ADHD was granted a de novo 510(k) classification by the FDA (K112711). The device is indicated to measure the theta/beta ratio of the electroencephalogram at electrode CZ on patients 6 to 17 years of age, combined with a clinician’s evaluation, to aid in the diagnosis of ADHD. 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 clinical evaluation. The device is not intended as a stand-alone tool in the evaluation or diagnosis of ADHD. FDA product code: NCG

Rationale

Background

Attention-Deficit/Hyperactivity Disorder

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 (e.g., 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 substantial research conducted 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 are increased theta wave activity and an increased theta/beta ratio in ADHD patients.

The Neuropsychiatric EEG-based ADHD Assessment Aid (NEBA®) system is a specific quantitative EEG system that measures the resting theta/beta ratio of the electroencephalogram with an electrode located at the central midline position (referred to as position CZ in the international 10-20 EEG system). Quantitative EEG uses computer analysis with the mathematical transformation from the time domain into the frequency domain (fast-Fourier transform) to determine the total power at each frequency. The relative power of the waveform can then be calculated in relation to the total
Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder

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power of the 4 frequency ranges. The NEBA 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 for 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. Also, as a result of research on EEG brain waves in ADHD, neurofeedback has been developed as a potential treatment for ADHD (see Blue Shield of California Medical Policy: Neurofeedback). This treatment employs principles of biofeedback using EEG brain wave activity and attempts to alter the brainwave patterns in beneficial ways.

Literature Review
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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Quantitative Electroencephalography
Clinical Context and Test Purpose
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.

The purpose of quantitative electroencephalography (EEG) in individuals who are suspected of having ADHD is to inform a decision whether to initiate specific therapy.

The following PICO was used to select literature to inform this review.

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

**Interventions**
The test being considered is quantitative EEG, using the Neuropsychiatric EEG-based ADHD Assessment Aid (NEBA) system, as part of a clinical evaluation. Devices that provide neurofeedback are also able to assess the theta/beta ratio with quantitative analysis.
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.

Study Selection Criteria
For the evaluation of the clinical validity of the tests, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described
- Included a validation cohort separate from development cohort.

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).

Review of Evidence
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 versus nonclinical population. Quantitative reports of EEG used in the adult ADHD population have found no consistent evidence of atypical theta/beta ratios as a marker of ADHD. A TEC Assessment (2014) evaluated the evidence related to the use of quantitative EEG with the NEBA system in the diagnosis of ADHD. This evidence 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 is described next. The evidence also included a discussion of the technical performance of NEBA for the diagnosis of ADHD and 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 the FDA, improved health outcomes.

Cohort Studies
Data submitted to the FDA regarding the diagnostic accuracy of the NEBA system were from the multicenter study of 275 children and adolescents (aged 6-18 years, described above) who presented with attention and/or behavioral concerns to 1 of 13 clinics in the U.S. 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 parent rating scales, features considered critical for a criterion standard diagnosis of ADHD. A separate group of investigators who were unaware of the clinical diagnosis collected the EEG data (NEBA system). When compared with the consensus diagnosis, NEBA had a sensitivity of 89%, a specificity of 87%, a positive predictive
value of 81%, and negative predictive value of 93% for adolescents (aged 12-17 years). For children (ages 6-11 years), NEBA had a sensitivity of 79%, a specificity of 97%, a positive predictive value of 96%, and negative predictive value of 82%. The investigators calculated that the addition of NEBA to the clinician’s ADHD evaluation would have increased the clinician’s diagnostic accuracy from 61% to 88%. This calculation is based on the 275 patients who completed the protocol, rather than the intention-to-treat population. The results of this FDA-regulated study suggested that quantitative EEG might be used to decrease the overdiagnosis of ADHD by identifying patients who may not have the disorder. Strengths of this study included its multicenter design and the reclassification analysis of data obtained from a blinded analysis. Limitations were lack of patient interview by the consensus team and lack of intention-to-treat analysis.

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) aged 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 Diagnostic and Statistical Manual of Mental Disorders, 4th edition (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. An EEG was collected separately by investigators, who were 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 deviations of the theta/beta ratio from normative database values (according to age) at electrode CZ was used to determine ADHD versus non-ADHD. With a prevalence of ADHD of 61% based on clinical diagnosis, the theta/beta ratio had a sensitivity of 87%, a specificity of 94%, a 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 an analysis of data from the FDA-regulated study of the NEBA device.

Other studies have reported lower accuracy of quantitative EEG in the diagnosis of ADHD. van Dijk et al (2020) assessed whether different signal processing methods affected the ability to distinguish patients with ADHD from controls. Five different signal processing algorithms were applied to EEG screening data from 2 multi-center clinical studies: the International Collaborative ADHD Neurofeedback multisite clinical trial and the International Study to Predict Optimized Treatment in ADHD. The 2 studies included 608 children with ADHD and 158 children without ADHD. van Dijk et al found significant differences in the theta/beta ratio calculated with the 5 algorithms, but none of the methods were able to distinguish between children with and without ADHD. A limitation of this study is that methods used by NEBA were not specifically assessed.

**Section Summary: Clinically Valid**

Patients who have ADHD may have altered brain wave patterns on quantitative EEG compared with patients without ADHD. The most common alteration reported in clinical studies is an increased theta/beta ratio; however, not all studies have found this association. With regard to use of the NEBA system as part of a clinical evaluation, no studies have reported on sensitivity and specificity. In the pivotal study of the NEBA system, investigators calculated that the addition of NEBA to the clinician’s ADHD evaluation was estimated to increase diagnostic accuracy from 61% to 88%. However, there are limitations to the pivotal study including lack of an intention-to-treat approach and no patient interviews conducted by the consensus team. Additionally, a recent study of various EEG processing methods in a large dataset found no diagnostic value of the theta/beta ratio for children with ADHD, raising questions about the utility of quantitative EEG in 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.

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

The evidence related to whether quantitative EEG improves the clinical diagnosis of patients with suspected ADHD consists of the material submitted to the FDA as part of the NEBA’s approval process and subsequently published by Snyder et al (2015), as previously described.\(^3,4\) The study included reclassification tables to demonstrate whether NEBA provides additional information beyond the clinician’s initial diagnosis, which is 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.

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<th>Consensus Diagnosis</th>
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<td>NEBA interpretation</td>
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<td>95 (81.9)</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>21 (18.1)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>116</td>
</tr>
<tr>
<td>Not ADHD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEBA interpretation</td>
<td>+</td>
<td>8 (8.6)</td>
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<tr>
<td></td>
<td>-</td>
<td>85 (91.4)</td>
</tr>
<tr>
<td>Total</td>
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<td>93</td>
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</table>

ADHD: attention-deficit hyperactivity disorder; FDA: U.S. Food and Drug Administration; NEBA: Neuropsychiatric EEG-Based Assessment Aid.

\(^a\) The consensus diagnosis is assumed to be the reference standard (i.e., 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 (i.e., the NEBA interpretation cannot override it).

Section Summary: Quantitative Electroencephalography
Patients who have ADHD may have altered brain wave patterns on quantitative EEG compared with patients without ADHD. While an increased theta/beta ratio is the most common alteration reported,
not all studies have found this association. No studies have reported on the sensitivity and specificity of the NEBA system when added to clinical diagnosis. In the pivotal study, diagnostic accuracy was estimated to increase from 61% to 88% when added to clinical diagnosis. However, there are limitations to the pivotal study, and a recent study of various EEG processing methods in a large dataset found no diagnostic value of the theta/beta ratio for children with ADHD, raising questions about the utility of quantitative EEG in the diagnosis of ADHD. 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.

**Supplemental Information**
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

**Practice Guidelines and Position Statements**
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

**American Academy of Pediatrics**
The 2019 American Academy of Pediatrics’ practice guidelines on the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder (ADHD) was based on a systematic review from the Agency for Healthcare Research and Quality. The guidelines indicated that to make a diagnosis of ADHD, the primary care clinician should determine that *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, Text Revision*, criteria have been met (including documentation of impairment in more than 1 major setting), and information should be obtained primarily from reports from parents or guardians, teachers, and other school and mental health clinicians involved in the child’s care. The primary care clinician should also rule out any alternative cause (quality of evidence B/strong recommendation). Assessment by quantitative electroencephalography was not mentioned in these guidelines.

**American Academy of Neurology**
In 2016, the American Academy of Neurology released a technology report on quantitative electroencephalography for ADHD. The main conclusion of the report was that it remains “unknown whether a combination of standard clinical examination and EEG [electroencephalography] theta/beta power ratio increases diagnostic certainty of ADHD compared with clinical examination alone.”

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in August 2023 did not identify any ongoing or unpublished trials that would likely influence this review.
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.


Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

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<tr>
<td></td>
<td>95813</td>
<td>Electroencephalogram (EEG) extended monitoring; 61-119 minutes</td>
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<tr>
<td></td>
<td>95816</td>
<td>Electroencephalogram (EEG); including recording awake and drowsy</td>
</tr>
<tr>
<td></td>
<td>95819</td>
<td>Electroencephalogram (EEG); including recording awake and asleep</td>
</tr>
<tr>
<td></td>
<td>95957</td>
<td>Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)</td>
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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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**Definitions of Decision Determinations**

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements and Feedback (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue...
### POLICY STATEMENT

**BEFORE**

Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder 3.01.03

**Policy Statement:**

1. Quantitative electroencephalographic-based assessment of the theta/beta ratio is considered **investigational** as a diagnostic aid for attention-deficit/hyperactivity disorder.

**AFTER**

Quantitative Electroencephalography as a Diagnostic Aid for Attention-Deficit/Hyperactivity Disorder 3.01.03

**Policy Statement:**

1. Quantitative electroencephalographic-based assessment of the theta/beta ratio is considered **investigational** as a diagnostic aid for attention-deficit/hyperactivity disorder.