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Topographic Brain Mapping (Quantitative Electroencephalography)

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Topographic brain mapping (TBM), brain electrical activity mapping (BEAM), and quantitative electroencephalogram (QEEG), **may be considered medically necessary** when used as an adjunct to traditional electroencephalogram (EEG) when **ANY** of the following criteria is met:

- Evaluation of epilepsy when **ANY** of the following criteria is met:
  1. The surface or long-term EEG is inconclusive and additional testing for possible epileptic spikes or seizures is needed; or
  2. Ambulatory recording is needed to facilitate subsequent visual EEG interpretation; or
  3. There is need for topographic voltage and dipole analysis in pre-surgical candidates with intractable epilepsy; **OR**

- Continuous monitoring in the operating room for the early detection of an acute intracranial complication during cerebrovascular surgery (i.e., intracranial, carotid endarterectomy); **OR**
- Monitoring for the detection of nonconvulsive seizures in high risk patients in the intensive care unit and operating room; **OR**
- Evaluation of cerebral vascular disease (CVD), dementia and encephalopathy when **ANY** of the following criteria is met:
  1. Conventional testing has been completed without conclusive results; or
  2. The patient is not a candidate for radiologic testing (e.g., computed tomography [CT], magnetic resonance imaging [MRI], cerebral angiography).

NOTE 2: It is recommended that TBM /QEEG be administered and reviewed by physicians highly skilled in clinical TBM interpretation.

Topographic brain mapping (TBM), brain electrical activity mapping (BEAM), and quantitative electroencephalogram (QEEG) **are considered experimental, investigational and/or unproven** for all other indications (refer to **NOTE 3**) including but not limited to:

- Alcoholism;
- Chronic pain;
- Depression;
- Drug abuse;
- Hypoxic ischemic encephalopathy;
- Learning disability;
- Obsessive compulsive disorder;
- Post-concussion syndrome;
- Predicting response to psychotropic medication;
- Schizophrenia;
- Tinnitus.

Portable, non-invasive, point of care devices that record, analyze and display brain electrical activity (e.g., BrainScope One [Ahead 300], eVOX® System, COGNISION™**) are considered experimental, investigational and/or unproven** for all indications including, but not limited to the evaluation of individuals with suspected concussion and/or traumatic brain injury.

NOTE 3: State Legislation may apply. Carefully check for legislative mandates that may apply for each plan.

Policy Guidelines

There is no specific code for portable, non-invasive, point of care devices that record, analyze and display brain electrical activity.

Description

Topographic brain mapping (TBM), also known as brain electrical activity mapping (BEAM), and quantitative electroencephalogram (QEEG) is a visual enhancement of a traditional surface electroencephalogram (EEG). The brain mapping process transforms the surface EEG data into a pictorial mapping (i.e., topographic image) of the brain activity. Enhanced images are then placed on a schematic map of the brain, and the activity data is algorithmically analyzed and compared to a database of normal brainwave activity to determine patterns which distinguish pathological group from normal ones. (1)

Additionally, portable, non-invasive, point of care devices that utilize EEG data and advanced signal-processing to record and measure brain function are currently being used to analyze and display brain electrical activity in patients with various neurological and neurocognitive symptoms including but not limited to traumatic brain injury, post-concussion syndrome, dementia, and depression. Some devices include but are not limited to the BrainScope Device, the eVOX® System, and the COGNISION™ System. (2-4)

Regulatory Status

Topographic Brain Mapping/Quantitative Electroencephalogram (QEEG)

Multiple QEEG software packages have received United States (U.S.) Food and Drug Administration (FDA) approval under the 501(k)-approval process. Two examples include, but are not limited to, the NeuroGuide Analysis Software (K041263) and the Neurometric Analysis System (K974748). Refer to <https://accessdata.fda.gov> under FDA product code OLU for additional FDA approved software. (5, 6)

Devices that Record, Analyze and Display Brain Electrical Activity

The FDA granted 510(k) marketing clearance to BrainScope TBI (model: Ahead 500) in September 2019 (K190815), with BrainScope TBI (model: Ahead 400) as the predicate device (K183241). The FDA granted the original de novo classification to the original BrainScope (BrainScope Ahead 100) in August 2014. The de novo pathway is used for some low to moderate-risk medical devices that are not substantially equivalent to an already legally marketed device. FDA product codes: PIW, OLU, PKQ. (2)

On December 2017, the FDA approved the eVOX system as a class II device under the 510(k) process. The eVox System is a portable device intended for the acquisition, display and storage of electrical activity intended to help diagnose cognitive disorders, track cognitive status, and monitor disease progression. The device monitors brain health by QEEG and imaging, FDA product codes: GWQ, GWJ. (3)

On January 2017, the FDA approved the COGNISION System as a class II device under the 510(k) process. The COGNISION system should be used by qualified clinical professional for the acquisition, display, analysis, storage, reporting and management of EEG and auditory evoked potentials (AEP) information. FDA product codes: GWJ, OLT, OMC. (4)

Rationale

This policy was originally created in 1990 and has been updated regularly with searches of the PubMed database. Most recently, the literature was searched through March 6, 2023. Following is a summary of the key literature to date.

Topographic Brain Mapping
Topographic brain mapping (TBM) is being evaluated in a multitude of medical and psychological conditions.

Alcoholism
Evidence for the use of TBM in the evaluation of patients with alcoholism is insufficient to form conclusions about the impact on health outcomes. There are no long-term randomized controlled trials (RCTS) to support the use of TBM in patients with alcoholism. Comparative studies have been completed but they have small sample sizes. Additional adequately powered RCTs with sufficiently large sample sizes are needed.

Chronic Pain
Pinheiro et al. conducted a systematic review in 2016 of cross-sectional studies, longitudinal studies as well as clinical trials on electroencephalogram (EEG) patterns in individuals with chronic pain. (7) Primary findings related to chronic pain were an increase in theta and alpha EEG power at rest, and a decrease in the amplitude of evoked potentials after sensory stimulation and cognitive tasks. The authors concluded that increased alpha and theta power at spontaneous EEG and low amplitudes of event-related potentials during various stimuli appeared to be clinical characteristics of individuals with chronic pain. Quantitative electroencephalography (QEEG) can be a simple and objective tool for studying the mechanisms involved in chronic pain, identifying specific characteristics of chronic pain conditions and providing insights about appropriate therapeutic approaches. However, further clinical studies are needed to establish the clinical applicability of QEEG as an effective marker for diagnosis and guide to strategies for pain control. Systematic reviews with samples of individuals who have similar characteristics and type of pain can help define specific EEG patterns for each type of chronic pain.

Depression
In 2016, Arns et al. (8) completed the international Study to Predict Optimized Treatment in Depression (iSPOT-D) study in order to determine whether EEG occipital alpha and frontal alpha asymmetry (FAA) distinguishes patients with major depression disorder (MDD) from controls, predicts antidepressant treatment outcome. In this multi-center, randomized, prospective open-label trial, 1008 MDD participants were randomized to escitalopram, sertraline or venlafaxine-extended release. The study also recruited 336 healthy controls. Treatment response was established after 8 weeks and resting EEG was measured at baseline (2 minutes' eyes open and eyes closed). No differences in EEG alpha for occipital and frontal cortex, or for FAA, were found in MDD participants compared to controls. Alpha in the occipital and frontal

cortex was not associated with treatment outcome. However, a gender and drug-class interaction effect was found for FAA. Relatively greater right frontal alpha (less cortical activity) in women only was associated with a favorable response to the selective serotonin reuptake inhibitors escitalopram and sertraline. No such effect was found for venlafaxine-extended release. The study noted FAA does not differentiate between MDD and controls but is associated with antidepressant treatment response and remission in a gender and drug-class specific manner.

In 2017 Wang et al. (9) examined the aberrant EEG oscillation in major depressive patients with basal ganglia stroke with lesions in different hemispheres. Resting EEG of 16 electrodes in 58 stroke subjects, 26 of whom had post-stroke depression (PSD) (13 with left-hemisphere lesion and 13 with right-hemisphere lesion) and 32 of whom did not (18 with left lesion and 14 with right lesions), was recorded to obtain spectral power analysis for several frequency bands. Multiple analysis of variance and receiver operating characteristic (ROC) curves were used to identify differences between PSD and post-stroke non-depression (PSND), treating the different lesion hemispheres separately. Moreover, Pearson linear correlation analysis was conducted to test the severity of depressive symptoms and EEG indices. PSD with left-hemisphere lesion showed increased beta2 power in frontal and central regions, but PSD with right-hemisphere lesion showed increased theta and alpha power mainly in occipital and temporal regions. Additionally, for left-hemisphere lesions, beta2 power in central and right parietal regions provided high discrimination between PSD and PSND, and for right-hemisphere lesions, theta power was similarly discriminative in most regions, especially temporal regions. The researchers also explored the association between symptoms of depression and the power of abnormal bands but found no such relationship. The small study concluded that aberrant EEG oscillation in patients with PSD differs between patients with lesions of the left and right hemispheres, suggesting a complex association between depression and lesion location in stroke patients. The authors noted study limitations which included small study sample size which included subjects with different lesions of the basal ganglia.

Some research studies have shown a reproducible difference between groups of patients and normal subjects (e.g., increased frontal alpha in depression). Although progress is being made, these scientific observations are not necessarily directly relevant for clinical diagnosis in individual care situations. (1)

Drug Abuse

In 2006, Venneman et al. (10) examined pretreatment neurophysiological factors to identify participants at greatest risk during cocaine-dependent treatment. Twenty-five participants were divided into concordant and discordant groups following EEG measures recorded prior to a double-blind, placebo-controlled treatment trial. Three possible outcomes were examined: successful completion, dropout, and removal. Concordant (high perfusion correlate) participants had an 85% rate of successful completion, while discordant participants had a 15% rate of successful completion. Twenty-five percent of dropouts and 50% of participants removed were discordant (low perfusion correlate), while only 25% of those who completed

were discordant. Failure to complete the trial was not explained by depression, craving, benzoylecgonine levels or QEEG power; thus, concordance may help identify attrition risk.

Evidence for the use of TBM in patients with drug abuse includes multiple RCTS with small sample sizes. Additional adequately powered RCTs with sufficiently large sample sizes are needed to determine the impact on health outcomes.

Hypoxic Ischemic Encephalopathy

In 2010, Hathi et al. (11) accessed an EEG-based index and Cerebral Health Index in babies (CHI/b), for identification of neonates with high Sarnat staging scores and abnormal EEG as markers of hypoxic ischemic encephalopathy (HIE) after perinatal asphyxia. This retrospective study used 30 min of EEG data collected from 20 term neonates with HIE and 20 neurologically normal neonates. The HIE diagnosis was made on clinical grounds based on history and examination findings. The maximum-modified clinical Sarnat score was used to grade HIE severity within 72 hours of life. All neonates underwent 2 channel bedside EEG monitoring. A trained electroencephalographer blinded to clinical data visually classified each EEG as normal, mild or severely abnormal. The CHI/b was trained using data from Channel 1 and tested on Channel 2. The CHI/b distinguished among HIE and controls ($P<0.02$) and among the three visually interpreted EEG categories ($P<0.0002$). It indicated a sensitivity of 82.4% and specificity of 100% in detecting high grades of neonatal encephalopathy (Sarnat 2 and 3), with an area under the receiver operator characteristic (ROC) curve of 0.912. CHI/b also identified differences between normal verses mildly abnormal ($P<0.005$), mild verses severely abnormal ($P<0.01$) and normal verses severe ($P<0.002$) EEG groups. An ROC curve analysis showed that the optimal ability of CHI/b to discriminate poor outcome was 89.7% (sensitivity: 87.5%; specificity: 82.4%). The study concluded that the CHI/b identified neonates with high Sarnat scores and abnormal EEG. These results support its potential as an objective indicator of neurological injury in infants with HIE.

UpToDate

In 2020, UpToDate (12) researched available literature regarding hypoxic-ischemic brain injury in adults. The summary specified:

"The clinical value of the electroencephalogram (EEG) is unclear in the assessment of prognosis of anoxic brain injury because investigators have used different classification systems and variable intervals of recordings after resuscitation. Furthermore, the EEG is susceptible to subjective interpretation, the effects of sedative drugs, metabolic disturbances, and sepsis, which can invalidate the results. As a result, while EEG findings can be useful, they should be used in the context of other prognostic indicators." Additionally, UpToDate does not specifically mention of the use of QEEG in adult patients for the evaluation of hypoxic-ischemic brain injury.

Furthermore, in 2022, UpToDate published guidance which discusses the clinical features, diagnosis, and treatment of neonatal encephalopathy although it does not mention QEEG/topographic brain mapping as a diagnostic tool. (13)

Learning Disability

Neurophysiologic studies of children with learning disorders (LD) have shown that poor spellers, children with dyslexia, or hyperactive children have different neurophysiologic responses from those in groups of normal children. Relationships between a patient's EEG patterns and outcome of therapy have been proposed, but still await controlled verification. This research has been useful for scientific understanding of physical and physiologic differences between children with these disorders and normal children, although the studies vary in the kinds of changes reported and there have been questions raised about reproducibility. Diagnostic tests, including EEG brain mapping, have not been proven useful in establishing the diagnosis or treatment plan for individual children. No independent blinded comparisons have been made with a clinical standard. Many studies do not use an appropriate spectrum of patients for whom the diagnostic tests would be applied in clinical practice. There is no evidence that outcome was changed by the diagnostic testing or by the treatment plans predicated on such testing. Thus, there is no evidence that patients are better off for having had these tests performed. (1)

Chabot et al. (14) conducted a literature review to determine the efficacy of using TBM in children and adolescent psychiatric disorders. Most of the studies focused on children and adolescents with attention or learning problems. The researchers found other possible uses of TBM in determining appropriate medication selection following treatment response and delineating the underlying cause of specific psychiatric disorders; however, most of this data was obtained from specialized research documents. The authors also concluded that TBM may prove to be a valuable imaging technique that could be used in children with attention and learning problems. They suggested that TBM may be beneficial in differentiating between Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD) and LD, and may be useful in optimizing pharmacological treatment, remediation, or psychological interventions. The overall body of scientific evidence however, is of insufficient quantity and quality to support the use of TBM for these indications.

Obsessive Compulsive Disorder

In 2019, Perera et al. (15) noted that obsessive-compulsive disorder (OCD) is a chronic disease that causes significant decline in the quality of life (QOL). Due to the limited understanding of the underlying pathophysiology of OCD, successful treatment remains elusive. Although many have studied the pathophysiology of OCD through EEG, limited attempts have been made to synthesize and interpret their findings. In this systematic review, examiners conducted a comprehensive literature search using Medline/PubMed and considered the 65 most relevant studies published prior to June 2018. The findings were categorized into QEEG, sleep-related EEG and exposure response prevention (ERP) therapy. Increased frontal asymmetry, frontal slowing and an enhancement in the ERP known as error-related negativity (ERN) were consistent findings in OCD. However, sleep EEG and other ERP (P3 and N2) findings were inconsistent. Additionally, these examiners analyzed the usefulness of ERN as a potential candidate endophenotype. They hypothesized that dysfunctional frontal circuitry and over-active performance monitoring were the major underlying impairments in OCD. Additionally, the researchers conceptualized that defective fronto-striato-thalamic circuitry causing poor cerebral functional connectivity gave rise to the OCD behavioral manifestations. Finally, the

examiners discussed transcranial magnetic stimulation and EEG (TMS-EEG) applications are needed to further understand the underlying pathophysiology of OCD.

In 2022, UpToDate (16) published a review on OCD in adults which does not mention QEEG as a diagnostic and/or management tool.

Post-Concussion Syndrome

Several published studies have addressed EEG brain mapping and other QEEG analysis techniques in patients with head injury. Some reports are uncontrolled, unblinded, or retrospective observations, which are difficult to use for assessing clinical utility. Patients with extensive traumatic lesions, obvious on neuroimaging studies, had EEG and QEEG abnormalities. In the one small group of patients with post-concussion syndrome, an increase in 8 to 10 Hz alpha was reported. (15) A subsequent report described reduced alpha in a much larger group of patients after mild head injury. In the latter study, mild head-injury patients were separated from controls using a bayesian statistical discriminant formula weighted toward measurements of coherence and phase relationships as well as posterior alpha and frontotemporal beta activity. The authors replicated their findings with good sensitivity and specificity. Some individuals commented that this technique is predisposed to false-positive “abnormalities" in normal subjects due to mild drowsiness or other problems. Further independent long-term studies would be beneficial to determine the effect on health outcomes. (1)

In 2013 Kutcher et al. (17) evaluated the evidence for the use of QEEG, functional neuroimaging, head impact sensors, telemedicine and mobile devices in diagnosing and/or managing sports related concussion. Multiple databases were searched including MEDLINE, PubMed, Cochrane, SportDiscus, EMBASE, Web of Science and ProQuest databases. The initial search produced 8,567 publications and the secondary search produced 9 additional publications which presented original data, included a comparison group in the study design and involved sports-related concussion: 4 studies spoke to the potential of QEEG as a diagnostic or management tool, while 5 studies addressed the potential of functional magnetic resonance imaging (fMRI) to be used in the same capacity. The authors concluded that emerging technologies and novel approaches that aid in sports concussion diagnosis and management are being introduced at a rapid rate. Moreover, they stated that while some technologies show promise, the clinical utility remains to be established.

A subsequent report described reduced alpha in a much larger group of patients after mild head injury. In the latter study, mild head-injury patients were separated from controls using a bayesian statistical discriminant formula weighted toward measurements of coherence and phase relationships as well as posterior alpha and frontotemporal beta activity. The authors replicated their findings with good sensitivity and specificity. Some individuals commented that this technique is predisposed to false-positive “abnormalities" in normal subjects due to mild drowsiness or other problems. Further independent long-term studies would be beneficial to determine the effect on health outcomes. (1)

Predicting Response to Psychotropic Medication

Some investigators have proposed use of QEEG in psychiatric disorders to facilitate selection of medications. In 2005, Crumbley et al. (18) examined the use of QEEG in predicting response to psychotropic medications. The clinical outcomes of two groups of patients were compared to those with prescribed medication regimens that were concordant with the QEEG predictors, and those whose medication regimens were discordant with the QEEG predictors. Participants included 70 inpatient adolescents who were administered QEEG upon admission. The results indicated no significant difference in clinical outcome between the two groups. The failure of this study to find significant differences in patient outcomes questions the efficacy of QEEG.

In 2022, Singh et al. (19) sought to examine whether early changes in frontal and prefrontal theta value in QEEG could predict antidepressant treatment response in the Indian population. Structured clinical assessments were conducted at baseline and after one week in a sample of treatment-seeking adults with major depressive disorder (n = 50). Patients were started on SSRI (escitalopram, fluoxetine, paroxetine or sertraline) and followed for 8 weeks. QEEG recordings were carried out at baseline and week 1 and its parameters (relative theta power and cordance) were assessed to identify its predictive value for treatment response. Treatment response was assessed using Hamilton depression rating scale with 50% reduction after 8 weeks being considered as response. The mean age of the sample was 39 ± 10 years with 64% females. A significant reduction was found in relative frontal theta value ($p = 0.021$) from baseline to one week in responders. However, linear regression revealed that this change could not predict the treatment response ($p = 0.37$). The authors concluded that QEEG changes were observed in initial phase of antidepressant treatment, but these changes cannot predict treatment response.

There is a lack of reliable evidence from large RCTs demonstrating that clinical outcomes are improved by basing selection of psychotropic medications on QEEG results compared to empiric selection. Additional long-term studies with larger sample sizes are warranted to determine the impact on health outcomes.

Schizophrenia

In 2014, Fuggetta et al. (20) aimed to evaluate QEEG measures of power spectra as potential biomarkers of the predisposition towards the development of psychosis in schizotypal individuals. The resting-state oscillatory brain dynamics under eyes-closed condition from 16 low schizotypy (LoS) and 16 high schizotypy (HiS) individuals were analyzed for QEEG measures of background rhythm frequency (relative power in δ, θ, low-α, high-α, low-β, high-β and low-γ frequency bands) and the high-temporal cross-correlation of power spectra between low- and high-frequency bands observed by averaging signals from whole-head EEG electrodes. HiS individuals at rest locked the thalamocortical loop in the low-α band at a lower-frequency oscillation and displayed an abnormally high level of neural synchronization. In addition, the high-α band was found to be positively correlated with both the high-β and low-γ bands unlike LoS individuals, indicating widespread thalamocortical resonance in HiS individuals. The increase of regional alpha oscillations in HiS individuals suggests abnormal high-level attention, whereas the pattern of correlation between frequency bands resembles the thalamocortical

dysrhythmia phenomenon which underlies the symptomatology of a variety of neuropsychiatric disorders including schizophrenia. These QEEG biomarkers may aid clinicians in identifying HiS individuals with a high-risk of developing psychosis.

In 2015, Kim et al. (21) evaluated the QEEG characteristics of patients with un-medicated schizophrenia (SPR) and to investigate the diagnostic utility of QEEG in assessing such patients during resting conditions. The subjects included 90 patients with schizophrenia and 90 normal controls. Spectral analysis was performed on the absolute power of all the electrodes across 5 frequency bands following artifact removal. The authors conducted a repeated-measures analysis of variance (ANOVA) to examine group differences within the 5 frequency bands across several brain regions and receiver operator characteristic analyses to examine the discrimination ability of each frequency band. Compared with controls, patients with schizophrenia showed increased delta and theta activity and decreased alpha 2 activity, particularly in the frontocentral area. There were no significant differences in the alpha 1 and beta activity. The receiver operator characteristic analysis performed on the delta frequency band generated the best result, with an overall classification accuracy of 62.2%. The results of this study confirmed the characteristics of the QEEG power in un-medicated schizophrenia patients compared with normal controls. These findings suggest that a resting EEG test can be a supportive tool for evaluating patients with schizophrenia.

In 2019, McVoy et al. (22) noted that QEEG has emerged as a potential intermediate biomarker for diagnostic clarification in mental illness. In a systematic review, these researchers examined published studies that used QEEG in youth with psychiatric illness between 1996 and 2017. They conducted a comprehensive database search of multiple databases which located a total of 2,268 youth aged 4 to 18 years that met the inclusion criteria. QEEG was most frequently studied as a potential diagnostic tool in pediatric mental illness although few studies assessed therapeutic response. The most consistent finding in autism spectrum disorder (ASD) was decreased coherence in ASD compared to healthy controls. Studies showed MDD has lower temporal coherence and inter-hemispheric coherence in sleep EEGs than in healthy controls. The authors concluded that further research is needed in the areas of mood, anxiety, ASD, and relationship to treatment. It remained unknown if abnormalities in QEEG were non-specific markers of pediatric psychiatric illness or if they have the potential to differentiate types of psychopathology.

To date, the evidence is insufficient to draw conclusions about the impact on health outcomes for the use of QEEG for individuals diagnosed with schizophrenia.

Tinnitus

In 2007, Ashton et al. (23) studied high frequency localized "hot spots" in temporal lobes of patients with intractable tinnitus. Tinnitus, which is the perception of noise in the absence of an external auditory stimulus, is associated with several conditions. Brain imaging studies indicate increased neuronal excitability and decreased density of benzodiazepine receptors in temporal (auditory) cortex but the source and mechanism of such changes are unknown. Various EEG abnormalities involving temporal lobe and other brain areas have been described

but recordings have been limited to standard EEG wave bands up to frequencies of 22Hz. This clinical study of otherwise healthy patients with intractable unilateral tinnitus, using QEEG, identified discrete localized unilateral foci of high frequency activity in the gamma range (>40-80Hz) over the auditory cortex in eight patients experiencing tinnitus during recording. These high frequency "hot spots" were not present in 25 subjects without tinnitus. The results suggest that further EEG investigations should include recordings in the gamma frequency range since such high frequency oscillations are believed to be necessary for perception. Identification of "hot spots" in tinnitus patients would provide a means for monitoring the effects of new treatments. These findings may also provide a model for exploration of more complex phenomena such as verbal and musical hallucinations.

Some small studies note that electroencephalograph activity differs between normal control subjects and subjects suffering from tinnitus. (24) Additional, larger, long-term evidence is needed to evaluate the value of including QEEG in a battery of electrophysiological tests for the clinical diagnosis of tinnitus.

Devices that Record, Analyze and Display Brain Electrical Activity (i.e., BrainScope System, eVOX® , COGNISION™)

In 2017, Hanley et al. (25) noted that a brain electrical activity biomarker for identifying traumatic brain injury (TBI) in emergency department (ED) patients presenting with high Glasgow Coma Scale (GCS) after sustaining a head injury has shown promise for objective, rapid triage. In a multicenter, observational study, investigators prospectively evaluated the efficacy of an automated classification algorithm to determine the likelihood of being computed tomography (CT)-positive, in high-functioning TBI patients in the acute state. Adult patients admitted to the ED for evaluation within 72 hours of sustaining a closed head injury with GCS 12 to 15 were candidates for study. A total of 720 patients (18 to 85 years of age) meeting inclusion/exclusion criteria were enrolled in this validation trial at 11 United States (U.S.) EDs; GCS was 15 in 97 %, with the 1st and 3rd quartiles being 15 (interquartile range [IQR] =0) in the study population at the time of the evaluation. Standard clinical evaluations were conducted, and 5 to 10 minutes of EEG was performed from frontal and frontal-temporal scalp locations. Using a priori derived EEG-based classification algorithm developed on an independent population and applied to this validation population prospectively, the likelihood of each subject being CT+ was determined, and performance metrics were computed relative to adjudicated CT findings. Sensitivity of the binary classifier (likely CT+ or CT-) was 92.3 % (95 % confidence interval [CI]: 87.8 % to 95.5 %) for detection of any intra-cranial injury visible on CT (CT+), with specificity of 51.6 % (95 % CI: 48.1 % to 55.1 %) and negative predictive value (NPV) of 96.0 % (95 % CI: 93.2 % to 97.9 %). Using ternary classification (likely CT+, equivocal, likely CT-) demonstrated enhanced sensitivity to traumatic hematomas (greater than or equal to 1 ml of blood), 98.6 % (95 % CI: 92.6 % to 100.0 %), and NPV of 98.2 % (95 % CI: 95.5 % to 99.5 %). The authors concluded that using an EEG-based biomarker high accuracy of predicting the likelihood of being CT+ was obtained, with high NPV and sensitivity to any traumatic bleeding and to hematomas; specificity was significantly higher than standard CT decision rules. They stated that the short time to acquire results and the ease of use in the ED environment

suggested that EEG based classifier algorithms have potential to impact triage and clinical management of head-injured patients.

In 2017 Hack et al. (26) performed a diagnostic cohort study to compare the predictive power using an algorithm (which includes loss of consciousness [LOC] and amnesia) to the predictive power of LOC alone or LOC plus traumatic amnesia. ED patients 18 to 85 years presenting within 72 hours of closed head injury, with GSC 12 to 15, were study candidates. A total of 680 patients with known absence or presence of LOC were enrolled (145 CT+ and 535 CT patients); 5 to 10 mins of eyes closed EEG was acquired using the Ahead 300 hand-held device, from frontal and fronto-temporal regions. The same classification algorithm methodology was used for both the EEG-based and the LOC-based algorithms. Predictive power was evaluated using area under the ROC curve (AUC) and odds ratio (OR). The QEEG-based classification algorithm demonstrated significant improvement in predictive power compared with LOC alone, both in improved AUC (83 % improvement) and OR (increase from 4.65 to 16.22). Adding retrograde amnesia (RGA) and/or post-traumatic amnesia (PTA) to LOC was not improved over LOC alone. The authors concluded that rapid triage of TBI relies on strong initial predictors. Addition of an EEG-based marker was shown to outperform report of LOC alone or LOC plus amnesia, in determining risk of an intra-cranial bleed. Moreover, they stated that ease of use at point-of-care, non-invasive, and rapid result using such technology suggested significant value added to standard clinical prediction.

In 2018, the potential clinical utility of a QEEG-based Brain Function Index (BFI) as a measure of the presence and severity of functional brain injury was studied as part of an independent prospective validation trial by Hanley et al. (27) The BFI was derived using QEEG features associated with functional brain impairment reflecting current consensus on the physiology of concussive injury. A total of 720 adult patients (18 to 85 years of age) were evaluated within 72 hours of sustaining a closed head injury were enrolled at 11 U.S. EDs; GCS score was 15 in 97% of the patients. Standard clinical evaluations were conducted, and 5 to 10 minutes of EEG acquired from frontal locations. Clinical utility of the BFI was assessed for raw scores and percentile values. A multinomial logistic regression analysis demonstrated that the ORs (computed against controls) of the mild and moderate functionally impaired groups were significantly different from the OR of the CT-positive (CT+, structural injury visible on CT) group ($p = 0.0009$ and $p = 0.0026$, respectively). However, no significant differences were observed between the ORs of the mild and moderately functionally impaired groups. Analysis of variance (ANOVA) demonstrated significant differences in BFI among normal (16.8 %), mild TBI (mTBI)/concussed with mild or moderate functional impairment, (61.3 %), and CT+ (21.9 %) patients (p potential to aid in early diagnosis and thereby potential to impact the sequelae of TBI by providing an objective marker that is available at the point-of-care, hand-held, non-invasive, and rapid to obtain.

In 2018 Jacquin et al. (28) acknowledged that there is no gold standard for the diagnosis of concussion therefore prompt, accurate, objective assessment is critical, particularly in children and young adults. In this study, concussed subjects (N = 177), matched controls (N = 187) and healthy volunteers (N = 204) represented a convenience sample of male and female subjects

between the ages of 13 and 25 years, enrolled at 48 Colleges and High Schools in the U.S. Subjects were tested at time of injury and at multiple time points during recovery. Assessments included EEG, neurocognitive tests and standard concussion assessment tools. Multimodal classifiers to maximally separate controls from concussed subjects with prolonged recovery (≥14 days) were derived using QEEG, neurocognitive and vestibular measures, informed feature reduction and a Genetic Algorithm methodology for classifier derivation. The methodology protected against overtraining using an internal cross-validation framework. An enhanced multimodal BFI (eBFI) was derived from the classifier output and mapped to a percentile scale which expressed the index relative to non-injured controls. At time of injury eBFIs were significantly different between controls and concussed subjects with prolonged recovery, showing return to non-concussed levels at return-to-play plus 45 days. For the combined concussed population, and for the short recovery subjects, a more rapid recovery was noted. This manufacture funded study stated that multivariate, multimodal, objective index of brain function impairment can potentially be used, along with other tools, to aid in diagnosis, assessment, and tracking of recovery from concussion.

In 2018 Conley et al. (29) noted that sports-related concussion is associated with a range of short-term functional deficits that are commonly thought to recover within a 2-week post-injury period for most, but certainly not all, persons; and resting state electroencephalography (rs-EEG) may prove to be an affordable, accessible, and sensitive method of assessing severity of brain injury and rate of recovery following a concussion. A systematic review of articles published in the English language, up to June 2017, was retrieved. Observational, cohort, correlational, cross-sectional, and longitudinal studies were included. A total of 16 articles met inclusion criteria, which included data on 504 athletes and 367 controls. All 16 articles reported some abnormality in rs-EEG activity after a concussion; however, the cortical rhythms that were affected varied. The authors concluded that despite substantial methodological and analytical differences across the 16 studies, the review suggested that rs-EEG may provide a reliable technique to identify persistent functional changes in athletes after a concussion. Moreover, they stated that because of the varied approaches, however, considerable work is required to establish a systematic methodology to assess its efficacy as a marker of return-to-play.

In 2019, a UpToDate review (30) on “Acute mild traumatic brain injury (concussion) in adults” did not mention BrainScope/EEG-based technology as a diagnostic tool.

In 2022 ECRI (2) published a clinical evidence assessment specific to the use of BrainScope in the diagnosis of TBI which states available evidence is “inconclusive: too few data on outcomes”. ECRI states available studies provide insufficient evidence to determine BrainScope’s clinical utility for managing patients with concussion symptoms, and there is no data available on how BrainScope affects patient management/health outcomes.

In 2022, Ganapathi et al. (31) sought to distinguish between subjective cognitive decline (SCD), mild cognitive impairment (MCI), and dementia in a scalable, accessible way in order to promote early detection and intervention. They investigated diagnostic categorization using an FDA-cleared QEEG/event- related potential (qEEG/ERP)-based cognitive testing system (eVox®

by Evoke Neuroscience) combined with an automated volumetric magnetic resonance imaging (vMRI) tool (Neuroreader® by Brainreader). Patients who self-presented with memory complaints were assigned to a diagnostic category by dementia specialists based on clinical history, neurologic exam, neuropsychological testing, and laboratory results. In addition, qEEG/ERP (n = 161) and quantitative vMRI (n = 111) data were obtained. A multinomial logistic regression model was used to determine significant predictors of cognitive diagnostic category (SCD, MCI, or dementia) using all available qEEG/ERP features and MRI volumes as the independent variables and controlling for demographic variables. Area under the Receiver Operating Characteristic curve (AUC) was used to evaluate the diagnostic accuracy. The qEEG/ERP measures of reaction time, commission errors, and P300b amplitude were significant predictors (AUC= 0.79) of cognitive category. Diagnostic accuracy increased when volumetric MRI measures, specifically left temporal lobe volume, were added to the model (AUC= 0.87). This study demonstrated the potential of a primarily physiological diagnostic model for differentiating SCD, MCI, and dementia using qEEG/ERP-based cognitive testing, especially when combined with volumetric brain MRI. The accessibility of qEEG/ERP and vMRI means that these tools may be used as adjuncts to clinical assessments to help increase the diagnostic certainty of SCD, MCI, and dementia. The authors suggest additional studies to replicate these findings in a larger diverse sample.

eVOX® and *COGNISION™* devices are being used in individuals with neurocognitive disorders, including but not limited to, dementia, traumatic brain injury, and PTSD however, current evidence is insufficient to draw conclusions about the impact on health outcomes for the use of these devices.

Summary of Evidence

Topographic Brain Mapping

Topographic brain mapping (TBM), brain electrical activity mapping (BEAM), and quantitative electroencephalogram (QEEG) may be considered medically necessary when used as an adjunct to traditional electroencephalogram (EEG) for the evaluation of epilepsy, for continuous monitoring in the operating room for the early detection of an acute intracranial complication during cerebrovascular surgery, for monitoring for the detection of nonconvulsive seizures in high risk patients in the intensive care unit and operating room, and for the evaluation of cerebral vascular disease (CVD), dementia and encephalopathy when the criteria is met. There is insufficient evidence in the published, peer-reviewed literature to support the use of QEEG or TBM in clinical situations other than those currently recognized by the American Academy of Neurology (AAN) and the American Clinical Neurophysiology Society (ACNS) including but not limited to alcoholism, chronic pain, depression, drug/substance abuse, hypoxic ischemic encephalopathy (HIE), learning disability, obsessive compulsive disorder (OCD), post-concussion syndrome, predicting response to psychotropic medication, schizophrenia and tinnitus.

Devices that Record, Analyze and Display Brain Electrical Activity (e.g., Brainscope, eVOX® System, COGNISION™)

Devices that record, analyze and display brain electrical activity (i.e., Brainscope, eVOX® System, COGNISION™) are considered experimental, investigational and/or unproven as the evidence is insufficient to draw conclusions about the impact on health outcomes.

Practice Guidelines and Position Statements

American Academy of Neurology (AAN)

In 1997, a report by the AAN and the American Clinical Neurophysiology Society (1) offers guidance specific to the assessment for digital EEG, QEEG and brain mapping which provide the following recommendations:

Certain QEEG techniques are considered established as an addition to digital EEG to include:

1. Epilepsy: For screening for possible epileptic spikes or seizures in long-term EEG monitoring or ambulatory recording to facilitate subsequent expert visual EEG interpretation. (Class I and II evidence, Type A recommendation)
2. Operating room (OR) and intensive care unit and (ICU) monitoring: For continuous EEG monitoring by frequency-trending to detect early, acute intracranial complications in the OR or ICU, and for screening for possible epileptic seizures in high-risk ICU patients. (Class II evidence, Type B recommendation)

Certain QEEG techniques are considered possibly useful practice options as an addition to digital EEG in:

1. Epilepsy: For topographic voltage and dipole analysis in presurgical evaluations. (Class II evidence, Type B recommendation). The application of brain mapping is discussed in numerous textbooks and incorporated in several practice parameters in relation to the diagnosis of patients with epilepsy, the quantitative monitoring of patients during cranial surgery, or when monitoring high-risk patients in an ICU. TBM is a useful adjunct to a surface EEG and provides additional detail that can confirm the diagnosis of seizure-like activity, when performed and analyzed by a specially trained diagnostician.
2. Cerebrovascular Disease: Based on Class II and III evidence, QEEG in expert hands may possibly be useful in evaluating certain patients with symptoms of cerebrovascular disease whose neuroimaging and routine EEG studies are not conclusive. (Type B recommendation)
3. Dementia: Routine EEG has long been an established test used in evaluations of dementia and encephalopathy when the diagnosis remains unresolved after initial clinical evaluation. In occasional clinical evaluations, QEEG frequency analysis may be a useful adjunct to interpretation of the routine EEG when used in expert hands. (Class II and III evidence as a possibly useful test, Type B recommendation)

QEEG may possibly be useful in the evaluation of select patients with cerebrovascular disease (CVD), dementia and/or encephalopathy. For most patients, computerized axial tomography (CT) and magnetic resonance imaging (MRI) remain the test of choice for patients with CVD. QEEG has no clear medical indication in the evaluation of patients with CVD when a MRI, CT, and/or routine EEG are available. Patients that may benefit from QEEG include individuals where an EEG is not available in their community, patients who are too ill to travel to a neuroimaging location, and patients whom the neuroimaging tests are nonlocalizing, but substantial clinical suspicion of focal cerebral dysfunction remains. QEEG may possibly be

useful in evaluating patients with symptoms of CVD whose neuroimaging and routine EEG studies are not conclusive (Type B recommendation).

Based on current clinical literature, opinions of most experts, and proposed rationales for their use, QEEG remains investigational for clinical use in post-concussion syndrome, mild or moderate head injury, learning disability, attention disorders, schizophrenia, depression, alcoholism, and drug abuse. (Class II and III evidence, Type D recommendation)

Due to the substantial risk of erroneous interpretations, it is unacceptable for any EEG brain mapping or other QEEG techniques to be used clinically by those who are not physicians highly skilled in clinical EEG interpretation. (Strong Class III evidence, Type E recommendation). QEEG should be used only as an adjunct to and in conjunction with traditional EEG interpretation. These tests may be clinically useful only for patients who have been well selected based on their clinical presentation.

QEEG remains investigational for clinical use in post-concussion syndrome, mild-to-moderate head injury, learning disability, attention disorders, schizophrenia, depression, alcoholism, and drug abuse. Clinical studies have demonstrated distinctive forms of brain electrical activity in psychiatric conditions including but not limited to schizophrenia, major depression, and OCD. However, the clinical significance of these distinctive patterns of brain wave activity is unknown. Thus, the role of QEEG in diagnosis, evaluation of disease progression, and treatment of these conditions has yet to be elucidated.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	95812, 95813, 95816, 95819, 95830, 95955, 95961, 95962, 95999
HCPCS Codes	S8040

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
07/15/2024	Reviewed. No changes.
05/01/2023	Document updated with literature review. The following change was made in Coverage: modified language from "Portable, non-invasive, point of care devices which record and measure brain function, analyze and display brain electrical activity (e.g., BrainScope One [Ahead 300]**)** are considered experimental, investigational and/or unproven for all indications including, but not limited to the evaluation of individuals with suspected concussion and/or traumatic brain injury to "Portable, non-invasive, point of care devices that record, analyze and display brain electrical activity (e.g., BrainScope One [Ahead 300], eVOX® System, COGNISION™) are considered experimental, investigational and/or unproven for all indications including, but not limited to the evaluation of individuals with suspected concussion and/or traumatic brain injury." Added references 3-6, 19, 30, 31; others updated.
12/01/2022	Reviewed. No changes.
06/15/2021	Document updated with literature review. The following changes were made in Coverage: 1) Added obsessive compulsive disorder under the current experimental, investigational and/or unproven statement for topographic brain mapping. 2) Added "Portable, non-invasive, point of care devices, which record and measure brain function, analyze and display brain electrical activity, (e.g., BrainScope One/Ahead 300) are considered experimental, investigational and/or unproven for all indications including, but not limited to the evaluation of individuals with suspected concussion and/or traumatic brain injury." 3) Combined Note 1 and Note 3. Added references 2, 4, 7, 11, 13, 14, 16, 20, 22-27; others updated.
05/01/2020	Document updated with literature review. The following change was made to Coverage: Added chronic pain as an example to the list of experimental,

	investigational and/or unproven indications. Reference 12 revised; added reference 13; some removed.
07/15/2018	Reviewed. No changes.
08/15/2017	Document updated with literature review. The following change was made to Coverage: Added hypoxic ischemic encephalopathy to the list of experimental, investigational and/or unproven indications.
03/01/2016	Reviewed. No changes.
08/01/2015	Document updated with literature review. The following was added to Coverage: 1) Evaluation of cerebral vascular disease (CVD), dementia and encephalopathy is considered medically necessary when any of the following criteria is met: a) Conventional testing has been completed without conclusive results; or b) The patient is not a candidate for radiologic testing (e.g. CT, MRI, cerebral angiography). The following was changed in Coverage: The diagnosis of epilepsy is no longer required for: 1) continuous monitoring in the operating room for the early detection of an acute intracranial complication during cerebrovascular surgery (i.e., intracranial, carotid endarterectomy); or 2) monitoring for the detection of nonconvulsive seizures in high risk patients in the intensive care unit and operating room attention. In addition, attention disorder was moved to a new medical policy (MED 205.040). The title changed from Topographic Brain Mapping.
04/15/2014	Literature reviewed. Coverage unchanged.
12/01/2013	Policy revised with literature review; ICD codes updated. Coverage unchanged.
05/15/2008	Policy revised without literature review; new review date only.
12/05/2006	Revised/updated entire document
07/01/2004	Revised/updated entire document
05/01/1996	Revised/updated entire document
07/01/1994	Revised/updated entire document
04/01/1994	Revised/updated entire document
05/01/1990	New medical document