
Medical Policy



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***Current Policy Effective Date: 11/1/26**
(See policy history boxes for previous effective dates)

Title: Sub-Scalp Bilateral Electroencephalography Analysis and Monitoring (i.e. Minder® System)

Description

Sub-scalp electroencephalography (EEG) is a prescription device which consists of implanted and externally worn components intended for continuously recording, transmitting, and storing EEG signals and purported to be of use in individuals with epilepsy, over extended periods of time (months to years). FDA approved applications (Minder) include use in drug resistant epilepsy who are intolerant or not indicated for more conservative monitoring tools.

Medical Policy Statement

Sub-scalp electroencephalography (EEG) for remote individual monitoring to evaluate drug resistant epilepsy is experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0956T	0957T	0958T	0959T	0960T	1004T
1005T	1006T	1007T	1008T	1009T	

Notes:

- *Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*
- *Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.*

Background

Electroencephalography (EEG) is a noninvasive diagnostic test that records the brain's electrical activity using electrodes placed on the scalp. The electrodes detect voltage fluctuations generated by neuronal activity and transmit these signals to a computer for analysis. EEG is commonly used in the evaluation of epilepsy to identify abnormal electrical discharges, characterize seizure types, and assist with treatment decisions. However, because EEG records only a snapshot of brain activity, its ability to capture a seizure depends on the duration of monitoring and the frequency of seizure occurrence. Routine EEG studies lasting 20 to 60 minutes have a relatively low yield for recording an actual seizure. A major limitation of traditional EEG is that seizures may not occur during the short recording period. Longer monitoring periods with the sub-scalp EEG systems have been purported to detect seizures that could have otherwise been missed. Sub-scalp bilateral EEG systems purport primary advantage over conventional scalp EEG as the ability to capture objective, long-term seizure activity outside of the hospital.

Interest in subscalp EEG technology extends beyond seizure detection and epilepsy management. Investigators have proposed that continuous EEG acquisition may facilitate the identification and monitoring of electrophysiologic biomarkers associated with neurological and neurobehavioral disorders, including cognitive impairment, movement disorders, psychiatric conditions, sleep disorders, and traumatic brain injury.

The Minder® sub-scalp EEG monitoring system (Epiminder Pty Ltd) is designed to provide continuous, long-term recording of brain electrical activity through two EEG channels that capture signals from both cerebral hemispheres. The system consists of an implanted sub-scalp device, an external behind-the-ear (BTE) processor, a mobile phone application, and a secure cloud-based platform. During implantation, the telemetry device is placed beneath the

scalp within a small burr hole, and an electrode array is positioned so that recording contacts lie over the bilateral parietal regions. The electrodes continuously record differential EEG signals, which are transmitted to the implanted telemetry unit. Using an inductive radiofrequency link, data are transferred to the external BTE processor, which also provides power to the implant. The BTE processor then transmits the data via Bluetooth to the Minder mobile application, allowing secure upload to cloud storage for remote review and analysis. In addition to EEG data, the system can collect audio and accelerometry information, which are stored and analyzed alongside EEG recordings. Data are curated on the cloud platform and used to train machine-learning algorithms capable of detecting epileptiform activity and supporting seizure forecasting, thereby enabling objective, continuous assessment of seizure burden and brain activity over extended periods.

Summary of Evidence

For individuals who have drug resistant seizures, subscalp implantable EEG systems represent an emerging technology capable of providing ultra-long-term recordings of cerebral electrical activity. Although numerous studies have identified EEG biomarkers associated with neurological and neurobehavioral disorders, the majority of evidence has been derived from conventional scalp EEG studies rather than implantable subscalp systems. Current evidence is insufficient to establish the clinical utility of subscalp EEG monitoring for non-epilepsy indications. No prospective controlled trials have demonstrated improved diagnostic accuracy, disease management, health outcomes, or net health benefit compared with standard clinical care. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

Epilepsy and Seizure Disorders

Haneef et al (2022) describe sub-scalp EEG as a technically promising platform for ultra-long-term EEG monitoring, particularly for objective seizure quantification and future seizure forecasting. A major potential benefit is more objective long-term seizure measurement, given that patient-reported seizure diaries are often incomplete or inaccurate. However, detecting more electrographic events does not, by itself, demonstrate improved outcomes. The review also highlights important limitations, including uncertain clinical utility, undefined patient-selection criteria, limited localization capability, procedural risks, and the need for validated automated analytics. These parameters support cautious adoption along with classification of this device as investigational for routine clinical use, particularly outside narrowly defined

epilepsy monitoring or research settings. Sub-scalp EEG should not be considered a substitute for established epilepsy diagnostic pathways.

Recent evidence suggests that sub-scalp bilateral EEG systems can provide continuous, long-term monitoring of cerebral electrical activity with accurate detection of epileptiform discharges and electrographic seizures. Prospective studies have demonstrated concordance between sub-scalp and conventional scalp EEG recordings, successful seizure quantification over months to years, and the ability to identify seizure cycles suitable for seizure forecasting. Emerging studies have also shown high accuracy of automated seizure detection algorithms when applied to long-term sub-scalp recordings. The largest published multicenter study reported favorable safety outcomes and reliable signal quality without serious device-related adverse events. While the technology appears promising for objective seizure monitoring, seizure forecasting, and potentially presurgical assessment, current evidence remains largely limited to feasibility studies, observational cohorts, and early clinical trials with small study groups ($n = 4$ to 26). The evidence regarding seizure forecasting remains preliminary and largely retrospective. Outcomes focused on signal quality, seizure capture, algorithm performance, and safety rather than patient-centered clinical outcomes. Unanswered questions revolve around the improvement in seizure control, sudden unexpected deaths in epilepsy, hospital and emergency department visits, improvement of surgical candidate selection and outcomes, medication management when compared to the current standard of care, and quality of life. Additional studies evaluating the impact of sub-scalp EEG monitoring on diagnosis, treatment decisions, seizure control, quality of life, and health outcomes are needed to establish clinical utility.

Neurobehavioral Disorders

Multiple studies have identified EEG abnormalities associated with depression, Attention Deficit Hyperactivity Disorder (ADHD), schizophrenia, and Obsessive Compulsive Disorder (OCD). Findings have included alterations in theta, alpha, beta, delta, and gamma frequency bands as well as machine-learning-derived EEG features that may correlate with diagnosis or treatment response. However, the published evidence consists primarily of observational studies using conventional scalp EEG, and findings have not been consistently replicated across patient populations. Standardized biomarkers and validated clinical decision algorithms are lacking. Additionally, no evidence demonstrates that management guided by subscalp EEG monitoring improves patient outcomes compared with standard clinical evaluation and treatment.

Dementia and Neurodegenerative Disorders

Quantitative EEG studies have demonstrated slowing of brain activity and changes in spectral power that correlate with cognitive impairment and disease severity in Alzheimer disease and other dementias. Some studies have suggested that EEG abnormalities may predict progression from mild cognitive impairment to dementia and may assist in distinguishing dementia subtypes. Similarly, EEG alterations have been associated with Parkinson disease severity and dementia risk. Despite these findings, evidence remains limited to short-term EEG studies, and no prospective studies have established the clinical utility of long-term subscalp monitoring. The impact of SITE-guided interventions on diagnostic accuracy, treatment selection, functional outcomes, or disease progression remains unknown.

Syncope

EEG slowing and background suppression are well-recognized physiologic responses during cerebral hypoperfusion associated with syncope. Continuous monitoring using subscalp EEG has been proposed as a means of distinguishing recurrent syncope from epileptic seizures. Although this application is biologically plausible, evidence supporting subscalp EEG for this indication is currently theoretical. Prospective studies demonstrating improved diagnostic accuracy or patient outcomes have not been published.

Sleep Disorders

EEG abnormalities during sleep have been associated with obstructive sleep apnea and other sleep-related conditions. Continuous subscalp EEG monitoring has been proposed as a means to assess sleep architecture and evaluate response to treatment. However, evidence supporting this application is limited to correlations identified in polysomnography and conventional EEG studies. Validation studies comparing SITE with standard sleep testing have not been completed.

Brain Tumors and Traumatic Brain Injury

Preliminary studies have identified EEG abnormalities associated with tumor burden, tumor progression, neurocognitive impairment, and outcomes following traumatic brain injury. Investigators have proposed that continuous subscalp EEG monitoring could identify disease progression or predict clinical deterioration before symptoms become evident. The available evidence is limited to exploratory studies, and there is insufficient evidence to determine whether such monitoring improves management decisions or health outcomes.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some clinical trials that might influence this review are listed in the Table below.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT07110337	Diagnosing Epilepsy To EffeCT Change (DETECT)	210	Jun 2027

Supplemental Information

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.

No major professional society (International League Against Epilepsy, American Academy of Neurology, American Clinical Neurophysiology Society, National Institute for Health and Care Excellence, or International Federation of Clinical Neurophysiology) has issued a dedicated clinical practice guideline specifically addressing sub-scalp or subcutaneous EEG monitoring for epilepsy/seizure management. Existing EEG guidelines focus on routine EEG, ambulatory EEG, and inpatient long-term video-EEG monitoring rather than implantable sub-scalp systems.

Regulatory Status

The Minder System (Epiminder Pty. Ltd) is a sub-scalp implanted electroencephalogram system for remote patient monitoring which received FDA approval (2024) via a De Novo Classification request. It is a prescription device indicated to acquire, transmit, and store EEGs continuously from patients between 18-75 years of age with drug resistant epilepsy who are intolerant or not indicated for more conservative monitoring tools. The Minder System is intended to aid in a physician's remote assessment and monitoring of the indicated patient's condition. Remote patient assessment and monitoring for this use is defined as the patient's EEG data is available for review by a healthcare provider located at a different location from the patient and where the data is being collected.

The medical use of the data acquired by the Minder System is to be performed under the direction and interpretation of a licensed medical professional. The Minder System does not provide any diagnostic conclusions about the patient's condition.”

Product code: SEM

The Epios™ system is still in the research and early feasibility stages and has not received FDA approval.

Government Regulations

National:

No National determination is available.

Local:

No Local determination is available.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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10. Stirling RE, Maturana MI, Karoly PJ, et al. Seizure Forecasting Using a Novel Sub-Scalp Ultra-Long Term EEG Monitoring System. *Front. Neurol*. 2021;12:713794. <https://doi.org/10.3389/fneur.2021.713794>.
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13. U.S. Federal Drug Administration. De Novo Classification request for Minder System. 2024. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN240062.pdf. Accessed July 7, 2026.
14. Weisdorf, S., Duun-Henriksen, J., Kjaer, T. W., & Hochberg, L. R. (2019). Subcutaneous EEG monitoring in epilepsy: Characteristics of chronic EEG recordings captured by a minimally invasive implantable device. *Clinical Neurophysiology*, 130(10), 1741–1749.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 9, 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/26	8/18/26		Joint policy established (slp/lk) Vendor managed: N/A

Next Review Date: 3rd Qtr, 2027

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SUB-SCALP BILATERAL ELECTROENCEPHALOGRAPHY ANALYSIS AND
MONITORING (I.E. MINDER® SYSTEM)

Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.