Medical Coverage Policy

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Electroencephalography

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INSTRUCTIONS FOR USE

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Overview

This Coverage Policy addresses ambulatory electroencephalography (EEG) for the diagnosis and management of seizure activity, digital EEG spike analysis, and remote monitoring of sub-scalp implanted EEG systems.

Coverage Policy

Ambulatory Electroencephalography

Ambulatory electroencephalography (EEG) following completion of a routine EEG is considered medically necessary for the diagnosis and management of seizure activity when ANY of the following criteria is met:

- inconclusive routine EEG
- suspected epilepsy when the history, clinical examination, and routine EEG is inconclusive
- suspected seizures of sleep disturbances
- individual with confirmed epilepsy who is experiencing suspected non-epileptic events
- classification of seizure type for the selection or adjustment of anti-epileptic medication
- exclusion of non-neurological causes of seizure-like activity
- seizures which are precipitated by naturally occurring cyclic events or environmental stimuli which are not reproducible in the hospital or clinic setting

Ambulatory EEG is not covered or reimbursable for the diagnosis and management of ANY other indication.

Digital EEG Spike Analysis

Digital EEG spike analysis (CPT® code 95957) performed in conjunction with a specialized EEG (i.e., 95830, 95954, 95955, 95958) is considered medically necessary.

Digital EEG spike analysis performed in conjunction with a sleep study or routine EEG is not covered or reimbursable for ANY indication.

Remote Monitoring of Sub-Scalp Implanted EEG Systems

Remote monitoring of a sub-scalp implanted EEG monitoring system for the diagnosis and management of seizure activity is considered experimental, investigational, or unproven.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Ambulatory Electroencephalography (EEG)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
95700	Electroencephalogram (EEG) continuous recording, with video when performed, setup, patient education, and takedown when performed, administered in person by EEG technologist, minimum of 8 channels
95705	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; unmonitored
95706	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance
95707	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance
95708	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored
95709	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance
95710	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance
95711	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; unmonitored
95712	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance
95713	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance
95714	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored
95715	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance
95716	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance
95717	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; without video
95718	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure

CPT®* Codes	Description
	detection, interpretation and report, 2-12 hours of EEG recording; with video (VEEG)
95719	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video
95720	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)
95721	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video
95722	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video (VEEG)
95723	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video
95724	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, with video (VEEG)
95725	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, without video
95726	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, with video (VEEG)

ICD-10-CM Diagnosis Codes	Description
F51.8	Other sleep disorders not due to a substance or known physiological condition
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus

ICD-10-CM Diagnosis Codes	Description
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.A01	Absence epileptic syndrome, not intractable, with status epilepticus
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus
G40.B01	Juvenile myoclonic epilepsy, not intractable, with status epilepticus
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus
G40.B11	Juvenile myoclonic epilepsy, intractable, with status epilepticus
G40.B19	Juvenile myoclonic epilepsy, intractable, without status epilepticus
G40.C01	Lafora progressive myoclonus epilepsy, not intractable, with status epilepticus
G40.C09	Lafora progressive myoclonus epilepsy, not intractable, without status epilepticus
G40.C11	Lafora progressive myoclonus epilepsy, intractable, with status epilepticus
G40.C19	Lafora progressive myoclonus epilepsy, intractable, without status epilepticus
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus
G40.801	Other epilepsy, not intractable, with status epilepticus

ICD-10-CM Diagnosis Codes	Description
G40.802	Other epilepsy, not intractable, without status epilepticus
G40.803	Other epilepsy, intractable, with status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus
G40.821	Epileptic spasms, not intractable, with status epilepticus
G40.822	Epileptic spasms, not intractable, without status epilepticus
G40.823	Epileptic spasms, intractable, with status epilepticus
G40.824	Epileptic spasms, intractable, without status epilepticus
G40.833	Dravet syndrome, intractable, with status epilepticus
G40.834	Dravet syndrome, intractable, without status epilepticus
G40.841	KCNQ2-related epilepsy, not intractable, with status epilepticus
G40.842	KCNQ2-related epilepsy, not intractable, without status epilepticus
G40.843	KCNQ2-related epilepsy, intractable, with status epilepticus
G40.844	KCNQ2-related epilepsy, intractable, without status epilepticus
G40.89	Other seizures
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.911	Epilepsy, unspecified, intractable, with status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus
G47.00	Insomnia, unspecified
G47.01	Insomnia due to medical condition
G47.10	Hypersomnia, unspecified
G47.14	Hypersomnia due to medical condition
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.30	Sleep apnea, unspecified
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified
G93.5	Compression of brain
G93.6	Cerebral edema
G93.82	Brain death
I60.00-I60.9	Nontraumatic subarachnoid hemorrhage
I61.9	Nontraumatic intracerebral hemorrhage, unspecified
I63.00-I63.9	Cerebral infarction
P91.60	Hypoxic ischemic encephalopathy [HIE], unspecified
P91.61	Mild hypoxic ischemic encephalopathy [HIE]
P91.62	Moderate hypoxic ischemic encephalopathy [HIE]
P91.63	Severe hypoxic ischemic encephalopathy [HIE]
R25.1	Tremor, unspecified
R25.2	Cramp and spasm
R25.3	Fasciculation
R25.8	Other abnormal involuntary movements
R25.9	Unspecified abnormal involuntary movements
R40.4	Transient alteration of awareness
R41.0	Disorientation, unspecified
R41.82	Altered mental status, unspecified

ICD-10-CM Diagnosis Codes	Description
R55	Syncope and collapse
R56.01	Complex febrile convulsions
R56.1	Post traumatic seizures
R56.9	Unspecified convulsions
R94.01	Abnormal electroencephalogram [EEG]
S06.2X0A-S06.2X9S	Diffuse traumatic brain injury

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Digital EEG Spike Analysis

Considered Medically Necessary when digital EEG spike analysis (Table 1) is performed in conjunction with a specialized EEG procedure (Table 2):

Table 1: Digital EEG Spike Analysis

CPT®* Codes	Description
95957	Digital analysis of electroencephalogram (EEG) (eg, for epileptic spike analysis)

Table 2: Specialized EEG

CPT®* Codes	Description
95830	Insertion by physician or other qualified health care professional of sphenoidal electrodes for electroencephalographic (EEG) recording
95954	Pharmacological or physical activation requiring physician or other qualified health care professional attendance during EEG recording of activation phase (eg, thiopental activation test)
95955	Electroencephalogram (EEG) during nonintracranial surgery (eg, carotid surgery)
95958	Wada activation test for hemispheric function, including electroencephalographic (EEG) monitoring

Not Covered or Reimbursable when digital EEG spike analysis (Table 1) is performed in conjunction with a sleep study or routine EEG (Table 3):

Table 3: Sleep Study or Routine EEG

CPT®* Codes	Description
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist

CPT®* Codes	Description
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95812	Electroencephalogram (EEG) extended monitoring; 41-60 minutes
95813	Electroencephalogram (EEG) extended monitoring; 61-119 minutes
95816	Electroencephalogram (EEG); including recording awake and drowsy
95819	Electroencephalogram (EEG); including recording awake and asleep
95822	Electroencephalogram (EEG); recording in coma or sleep only
95824	Electroencephalogram (EEG); cerebral death evaluation only

Remote Monitoring of Sub-Scalp Implanted EEG Systems

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
1008T	Remote monitoring of sub-scalp implanted continuous bilateral electroencephalography monitoring system, device fitting, initial set-up, and patient education in wearing of system and use of equipment
1009T	Remote monitoring of a sub-scalp implanted continuous bilateral electroencephalography monitoring system, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, up to 30 days of recording without video

General Background

Seizures are episodes of abnormal electrical activity in the brain caused by groups of nerve cells transmitting signals excessively or at the same time. Involuntary movements, altered sensations, emotional changes, impaired awareness, and loss of consciousness may occur. Recovery after a seizure varies, with some individuals returning to baseline quickly, while others experience symptoms such as fatigue, confusion, or weakness. Epilepsy is a chronic neurological condition that may be diagnosed when a person experiences recurrent seizures (National Institute of Neurological Disorders and Stroke, 2025).

Medical history, physical examination, developmental, neurological, and behavioral assessments, along with diagnostic testing, may be used to evaluate seizures, diagnose epilepsy, and help guide treatment. A routine electroencephalogram (EEG) is a commonly used test to detect abnormal electrical activity in the brain. Simultaneous video monitoring may be performed during a routine EEG to observe seizure behavior and help exclude other conditions that resemble epilepsy (National Institute of Neurological Disorders and Stroke, 2025).

Routine EEG is performed at a healthcare provider's office, hospital, or diagnostic laboratory. During the procedure, the patient lies on a bed or reclining chair, and electrodes are placed on the scalp. The electrodes are connected to a recording device that converts brain electrical activity into visual waveforms, which are displayed on a monitor or printed on paper. To minimize interference with the recording, the patient may be instructed to remain still with eyes closed. However, the patient may also be asked to perform specific tasks, such as deep breathing, viewing flashing lights, or sleeping during the test to help elicit or capture seizure-related activity (MedlinePlus, 2025). A routine EEG may take 30 to 60 minutes to complete.

Ambulatory EEG

Due to its limited duration, a routine EEG may not capture infrequent or intermittent seizure activity. Ambulatory EEG uses a portable recording device to allow extended monitoring, increasing the likelihood of detecting seizure-related activity. During the recording period (typically 24 to 72 hours), patients may continue their usual daily activities of living, including sleep. Simultaneous video monitoring may also be performed with ambulatory EEG. A push-button device enables patients or caregivers to annotate the EEG recording during clinical events, such as the onset of a seizure, enhancing the clinical utility of the data collected (Moeller, et al, 2025).

U.S. Food and Drug Administration (FDA)

An electroencephalograph is an FDA Class II device used to measure and record the electrical activity of the brain using electrodes placed on the head. Numerous electroencephalographs, with and without with video capability, are FDA 510(k) cleared for ambulatory EEG.

Device or Product	Identifier	Manufacturer	Decision Date
X-Series System	K131383	Advanced Brain Monitoring Inc.	11/27/2013
BWMini EEG	K131335	Neurovirtual USA, Inc.	2/3/2015
Trackit T4 EEG Amplifier	K172271	Lifelines Ltd.	5/4/2018
Cadwell Apollo System	K201819	Cadwell Industries, Inc.	9/29/2020
Cumulus Functional Neurophysiology Platform	K221963	Cumulus Neuroscience Limited	4/27/2023

*FDA product code: GWQ

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

The published peer-reviewed medical literature contains some evidence, primarily in the form of case series, to support the use of ambulatory EEG. While the supporting evidence is not robust, the use of ambulatory EEG has become a standard of care for the diagnosis and management of seizure activity in select individuals. (Michaeli, et al., 2024; Syed, et al., 2019; Carlson, et al., 2018; Kandler, et al., 2017; Keezer, et al., 2016; Hussain, et al., 2013; Wirrell, et al., 2008).

Michaeli et al. (2024) conducted a prospective observational study to assess the feasibility of home video-EEG in a pediatric population. Demographic, clinical, and quality data were compared to a control group undergoing in-hospital video-EEG monitoring. The study included 20 children age 2.1 to 17.2 years (mean: 9.57 ± 1.01) who underwent home video-EEG. Twelve of the children were female (60%). The control group included 20 children, aged 1.4 to 18.5 years

(mean: 10.2 ± 1.21) who underwent in-hospital video-EEG monitoring. Ten of the children in the control group were female (50%). Inclusion criteria for home video-EEG included no requirement for reduction of antiseizure medication, cardiorespiratory monitoring, or an intravenous line; no anticipated need for rescue medication; explicit patient or family preference; and ability to manage the required equipment. Outcome measures included quality of the EEG and video recordings using a 5-point scoring system rated by a single pediatric neurologist. The study results revealed a higher proportion of intellectual disability/autism (60% versus 25%; $p<0.05$) and developmental and epileptic encephalopathy (35% versus 0%; $p<0.05$) in the home video-EEG cohort. Self-limited childhood epilepsy was more prevalent in the control group (25% versus 0%; $p<0.05$). In the home video-EEG group, the reasons for referral were seizure localization and classification (55%), paroxysmal event classification (25%), and quantification of sleep epileptic activity (20 %). In the control group, the reasons for referral were seizure localization and classification (40%), paroxysmal event classification (40%), and quantification of sleep epileptic activity (20%) ($p>0.05$). EEG quality favored the home setting (median 5; interquartile range [IQR] 3.25 to 5 versus median 4; IQR 3 to 4; $p<0.05$). Video quality favored the control group (median 3; IQR 2.25 to 4 versus median: 5; IQR 4 to 5; $p < 0.01$). Habitual events were captured in 40% of children undergoing home video-EEG and 45% of children in the control group. The authors concluded that despite limitations in video recording quality, home video-EEG is a feasible and valuable option in this pediatric population, especially for children with special needs. Future technological developments and refinements in home video-EEG may address existing limitations and improve the overall quality of ambulatory monitoring. The study is limited by the single-center design, lack of randomization, single unblinded rater, and unvalidated scoring system.

Carlson et al. (2018) published the results of a prospective study that evaluated the diagnostic efficacy and technical quality of home video telemetry (HVT) in comparison with inpatient video telemetry (IVT) in a pediatric group. Included patients (n=62) were aged 18 years and younger with video telemetry of 24 to 72 hours. Thirty–three patients were in the HVT group, and 29 patients were in the IVT group. The aim of the study was to determine if the performance of HVT was comparable to that of IVT in a pediatric group in terms of diagnostic efficacy, recording quality, and acceptability to parents or caregivers. The diagnostic accuracy between the two groups was comparable, with 64% of HVT patients, and 62% of IVT patients, having typical attacks during the recording. Equipment difficulties occurred in 52% of HVT studies, which included camera positioning and failure to turn on the infrared button at night. This resulted in a loss of diagnostic information for 15% of patients. Author reported limitations of the study included the lack of randomization and the subjective nature of recording quality assessment by a variety of clinical physiologists. The authors concluded that in a pediatric setting, HVT is able to provide similar technical and diagnostic quality results when compared to IVT.

In a prospective study (n=72) by Keezer et al. (2016), the sensitivity of ambulatory EEG was reported to be 2.23 times greater than that of routine EEG ($p<0.0001$). Ambulatory EEG results have been reported to change clinical management in up to 51% of patients, with a median recording duration of 1.4 days (Faulkner, et al., 2012). Prolonged ambulatory EEG has been found to have a higher probability of recording an epileptic event relative to sleep-deprived EEG (15.2% versus 0%, respectively; $p=0.01$) (Liporace, et al., 1998).

Digital EEG Spike Analysis

Digital EEG spike analysis for topographic voltage and dipole analysis may be performed as part of a comprehensive presurgical evaluation for patients with intractable (e.g., medically refractory or drug-resistant) epilepsy. These techniques can assist in localizing the brain region responsible for abnormal electrical activity (epileptogenic zone) and help guide planned surgical resection. However, inpatient long-term video-EEG monitoring remains the best method for accurately

localizing the epileptogenic zone in surgical candidates (Misulis and Akkineni, 2026; Padin-Rosado, 2025; Abou-Khalil, et al., 2022; Hahn and Emerson, 2022).

Literature Review

According to authoritative medical textbooks, digital EEG spike analysis for topographic voltage and dipole analysis is considered an established diagnostic technique and may provide clinical utility as part of a comprehensive presurgical evaluation for patients with intractable (e.g., medically refractory or drug-resistant) epilepsy (Misulis & Akkineni, 2026; Padin-Rosado, 2025; Abou-Khalil et al., 2022; Hahn & Emerson, 2022). However, there is a lack of authoritative medical textbook or robust peer-reviewed literature supporting the use of digital EEG spike analysis for any indication outside of presurgical evaluation for intractable epilepsy.

Remote Monitoring of Sub-Scalp Implanted EEG Systems

Sub-scalp implanted EEG systems are an emerging technology for the diagnosis and management of seizure activity. These systems are intended to provide continuous EEG remote monitoring and data collection over an extended period of time (months to years), supporting detection of infrequent events, identification of long-term seizure patterns (e.g., circadian or multiday cycles), and potential seizure forecasting. Implantable, sub-scalp, continuous EEG monitoring requires implantation of an electrode-containing device beneath the scalp, but above the skull, during a minimally invasive outpatient procedure. The implanted device wirelessly transmits EEG data to an external receiver for remote monitoring by a physician. Patients may use a smartphone application or other device to annotate the EEG recording during clinical events, such as the onset of a seizure, to potentially enhance the clinical utility of the data collected (Epiminder Limited, 2025; Moeller, et al, 2025).

U.S. Food and Drug Administration (FDA)

On April 17, 2025, the Minder System (Epiminder Limited) received FDA De Novo authorization (DEN240062). This system is classified by the FDA as a sub-scalp implanted EEG system for remote patient monitoring (Class: II) (Product Code: SEM). The FDA noted the following indications for use:

- "The Minder System is an electroencephalographic (EEG) recording and transmitting device implanted under the scalp. 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."

Device or Product	Identifier	Manufacturer	Decision Date
Minder System	DEN240062	Epiminder Limited	4/17/2025

*FDA product code: SEM

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference

for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

Currently, there is insufficient high-quality evidence in the published, peer-reviewed, scientific literature to support the safety, efficacy, and clinical utility of sub-scalp implanted EEG systems for the diagnosis and management of seizure activity. Limited evidence suggests these devices are generally safe and have the potential to outperform scalp EEG. However, existing studies are small and at high risk of bias. The impact of sub-scalp implanted EEG systems on long-term epilepsy outcomes remains unproven. Larger, more robust prospective studies are needed to confirm safety, effectiveness, and clinical utility (Halliday, et al., 2025; ECRI; 2025).

Halliday et al. (2025) conducted a prospective, multicenter, first-in-human observational trial to evaluate the safety and performance of the Minder System for continuous long-term seizure monitoring in adults with epilepsy. The study enrolled 31 participants. Five participants withdrew from the study prior to device implantation and 26 participants (mean age: 45 years; range: 23 to 71) underwent implantation. Two participants withdrew from the study after implantation, due to interstate relocation and personal preference, leaving 24 participants completing follow-up. Inclusion criteria included participants aged 18 to 75, clinical diagnosis of focal or generalized epilepsy, a minimum of two clinically identifiable epileptic events per month, medical and neurological stability, EEG profile consistent with epilepsy diagnosis, and ability to maintain a seizure diary and seizure monitoring device alone, or with the assistance of a competent individual. Significant progressive disorders or unstable medical conditions, previously implanted neurostimulation devices, recent epilepsy surgery, significant psychiatric disorders, and surgical contraindications to implantation were reasons for exclusion. The primary outcome was the incidence of adverse events within the first 6 months post-implantation. Secondary outcomes included the identification and clarity of neurophysiological signals and seizures on sub-scalp versus one-week scalp video-EEG at weeks 4 and 24 post-implantation. Correspondence of sub-scalp EEG findings with seizure diary entries was also assessed. The device was activated within 14 days of implantation. The study results at 6 months revealed no serious device- or procedure-related adverse events. No device required explantation or reimplantation. There were 13 device-related adverse events reported for eight participants. Most of these adverse events were classified as mild. The most common device-related adverse events were scalp pain and/or headaches (eight adverse events in 5/26 participants; 19%). There were also two reports of scalp paresthesia and two reports of a lump at the site of the device. Most device-related adverse events were resolved by the end of the study (8/13; 62%). There were 23 procedure-related adverse events reported for 12 participants. Most of these were classified as mild. Procedure-related adverse events included self-limiting postoperative implant site pain, headaches, or paresthesias (9/26, 35%); and wound infection, wound dehiscence, skin ulceration, and subgaleal hematoma (n = 4/26; 15%). There were also eight adverse events associated with general anesthetic including nausea, abdominal pain, constipation, sore throat, back pain, and asymptomatic hypotension. Most procedure-related adverse events were resolved by the end of the study (21/23; 91%). All sleep spindles, chewing artifacts, interictal discharges, and electrographic seizures observed on scalp video-EEG were also identified on sub-scalp recordings, with higher clarity ratings for sub-scalp EEG ($p = 0.0025$). Electrographic seizures were identified for 31% of diary events. However, participant accuracy was observed to vary widely (29% ± 27%; range: 0% to 100%). Two participants were classified as device failures due to insufficient EEG data collection, one because cognitive impairment limited effective device use and the other because a thick scalp prevented proper magnetic coupling between the implant and wearable components. The authors concluded that the Minder System demonstrated safety and effectiveness for continuous long-term seizure monitoring in adults with epilepsy. Sub-scalp EEG recordings captured all normal neurophysiological signals, interictal epileptiform discharges, and

seizures concurrently observed on scalp video-EEG across various epilepsy types and pathologies. Sub-scalp EEG has the potential to enhance multiple aspects of epilepsy care, including diagnosis, medication optimization, surgical planning, clinical trial selection, outcome assessment, and seizure forecasting. Limitations of the study noted by the authors include the small number of seizures captured during monitoring, scalp EEG was analyzed using commercially available seizure detection software rather than undergoing review by a board-certified neurologist, only 31% of diary events were associated with electrographic seizures on sub-scalp recordings, and gaps in EEG data completeness. The study is also limited by the small sample size.

ECRI (2025) conducted a clinical evidence assessment of sub-scalp continuous EEG for treating epilepsy. The assessment included six studies (three diagnostic cohort studies and three case series) that reported on sub-scalp EEG safety and accuracy for detecting seizures. One case series involved the Minder System (Epiminder Limited) (Stirling, et al., 2021) and the other five studies involved devices under clinical investigation by UNEEG medical (Rubboli, et al., 2024; Djurhuus, et al., 2023; Remvig, et al., 2022; Weisdorf, et al., 2019) or Wyss Center (Van Maren, et al., 2024). ECRI concluded that the current evidence from the three diagnostic cohort studies and three case series was insufficient to determine the clinical validity or utility of sub-scalp EEG for managing epilepsy. These studies have a high risk of bias and include too few participants to establish safety or diagnostic accuracy. None of the studies evaluated treatment outcomes based on sub-scalp continuous EEG. findings. Larger, well-designed prospective studies are required to validate existing results and clarify the clinical value of sub-scalp continuous EEG.

Professional Societies/Organizations

American Academy of Neurology (AAN)

The Quality Standards Subcommittee of the AAN (1995; Reaffirmed 2025) published a practice parameter regarding EEG in the evaluation of headache that stated: "The EEG is not useful in the routine evaluation of patients with headache (guideline). This does not exclude the use of EEG to evaluate headache patients with associated symptoms suggesting a seizure disorder, such as atypical migrainous aura or episodic loss of consciousness. Assuming head imaging capabilities are readily available, EEG is not recommended to exclude a structural cause for headache (option)."

American Clinical Neurophysiology Society (ACNS)

ACNS (2008) published guidelines regarding long-term monitoring for epilepsy, including ambulatory EEG, which outlined specific indications, noting that the list is not all-inclusive, as special circumstances may warrant additional considerations:

"Diagnosis

1. Identification of epileptic paroxysmal electrographic and/or behavioral abnormalities. These include epileptic seizures, overt and subclinical, and documentation of interictal epileptiform discharges. EEG and/or behavioral abnormalities may assist in the differential diagnosis between epileptic disorders and conditions associated with intermittent symptoms because of nonepileptic mechanisms (e.g., syncope, cardiac arrhythmias, transient ischemic attacks, narcolepsy, other sleep disturbances, psychogenic seizures, other behavioral disorders).
2. Verification of the epileptic nature of the new "spells" in a patient with previously documented and controlled seizures.

Classification/Characterization

1. Classification of clinical seizure type(s) in a patient with documented but poorly characterized epilepsy.
2. Characterization (lateralization, localization, distribution) of EEG abnormalities, both ictal and interictal, associated with seizure disorders. Characterization of epileptiform EEG features, including both ictal discharges and interictal transients, is essential in the evaluation of patients with intractable epilepsy for surgical intervention.
3. Characterization of the relationship of seizures to specific precipitating circumstances or stimuli (e.g., nocturnal, catamenial, situation-related, activity-related). Verification and/or characterization of temporal patterns of seizure occurrence, either spontaneous or with respect to therapeutic manipulations (e.g., drug regimens).
4. Characterization of the behavioral consequences of epileptiform discharges as measured by specific tasks.

Quantification

1. Quantification of the number or frequency of seizures and/or interictal discharges and their relationship to naturally occurring events or cycles.
2. Quantitative documentation of the EEG response (ictal and interictal) to a therapeutic intervention or modification (e.g., drug alteration).
3. Monitoring objective EEG features are useful in patients with frequent seizures, particularly with absence and other seizures having indiscernible or minimal behavioral manifestations."

However, ACNS also noted that the recommended uses for ambulatory continuous EEG recording and ambulatory—selective, computer systems does not include presurgical evaluation: "Not appropriate—detailed characterization of EEG features as is required in presurgical evaluation."

National Institute for Health and Care Excellence (NICE)

NICE (2025) guidelines for diagnosing and managing epilepsy in children, young people and adults in primary and secondary care, and referral to tertiary services states: "If routine and sleep-deprived EEG results are normal and diagnostic uncertainty persists, consider ambulatory EEG (for up to 48 hours)."

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Seizures and epilepsy can affect individuals of any age, race, gender, and socioeconomic status. However, these conditions are more prevalent in young children and older adults. Epilepsy occurs most frequently in children, with the highest incidence during the first year of life. New cases of epilepsy progressively decline, until about age 10, and then stabilize. The rate of epilepsy begins to rise after age 55, as individuals experience strokes, brain tumors, or Alzheimer's disease, which may trigger seizures. Epilepsy occurs more frequently among Hispanic individuals compared to non-Hispanic individuals. Active epilepsy (seizures not fully controlled) is reported more often in

White individuals than in Black individuals. However, the lifetime prevalence of epilepsy is higher among Black individuals than among White individuals. About 1.5% of Asian Americans live with epilepsy. Men have a slightly greater likelihood of developing epilepsy than women. Seizures are common in people who have sustained traumatic brain injuries. Individuals who served in the armed forces with combat experience face an elevated risk of post-traumatic epilepsy. Lower socioeconomic status is associated with a higher likelihood of developing seizures and epilepsy. Additionally, differences regarding when and where individuals receive epilepsy healthcare have been observed across different racial backgrounds. These differences contribute to what is referred to as the "treatment gap," and may help explain racial differences in epilepsy (Epilepsy Foundation, 2022).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
LCD	First Coast Service Options, Inc.	Special EEG Tests (L34521)	1/8/2019
LCD	National Government Services, Inc.	EEG – Ambulatory Monitoring (L33399)	1/1/2020
LCD	Palmetto GBA	Special Electroencephalography (L33447)	9/19/2024

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Revised policy statement for digital EEG spike analysis performed in conjunction with a specialized EEG. • Revised policy statement for digital EEG spike analysis performed in conjunction with a sleep study or routine EEG. • Added policy statement for remote monitoring of sub-scalp implanted EEG monitoring system.	2/15/2026
Annual Revision	• No policy statement changes.	1/15/2025
Annual Revision	• No policy statement changes.	1/15/2024

Revision	• Revised policy statements for ambulatory and digital spike EEG 10/15/2023	10/15/2023