Regence

Medical Policy Manual Surgery, Policy No. 239

Long-Term Sub-Scalp Electroencephalography Monitoring Systems

Effective: July 1, 2025

Next Review: May 2026
Last Review: May 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Long-term sub-scalp electroencephalography monitoring systems are used to acquire, transmit, and store continuous EEGs for long periods of time (months to years) in patients with drug-resistant epilepsy.

MEDICAL POLICY CRITERIA

The use of long-term, sub-scalp electroencephalography monitoring systems (e.g., Minder®) for seizure monitoring is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

REGULATORY STATUS

The Minder® System from Epiminder received FDA De Novo classification on April 17, 2025.

EVIDENCE SUMMARY

Nonrandomized Studies

Weisdorf (2019) published a study of nine patients using a beta-version of a 24/7 sub-scalp EEQ monitoring device and gathered data on seizures, adverse events, compliance, and use of antiepileptic drugs.[1] Eight of the nine participants completed at least nine weeks of monitoring with one ending participation at four weeks due to postimplant soreness. There were 13 reports of device-reported adverse events with the authors reporting that none were serious. It was reported that seizure counts were substantially different than diary counts from the participants. This study is limited to its small sample size and non-randomized design.

There are numerous low-quality, non-randomized studies and reports that address the potential use of long-term sub-scalp EEG monitoring for patients with epilepsy.[2-7] These studies are significantly limited by small sample sizes, no comparison groups, lack of evaluation of the clinical utility of implantable long-term monitoring compared to standard EEG monitoring protocols, and non-randomized protocols.

PRACTICE GUIDELINE SUMMARY

No evidence-based clinical practice guidelines were identified which address the use of long-term, sub-scalp electroencephalography monitoring systems for seizure monitoring.

SUMMARY

There is not enough evidence to show that long-term, sub-scalp electroencephalography monitoring systems (e.g., Minder®) for seizure monitoring improve health outcomes in this population. There are no guidelines that recommend use of long-term, sub-scalp electroencephalography monitoring systems (e.g., Minder®) for seizure monitoring. Therefore, use of long-term, sub-scalp electroencephalography monitoring systems (e.g., Minder®) for seizure monitoring is considered investigational.

REFERENCES

1. Weisdorf S, Duun-Henriksen J, Kjeldsen MJ, et al. Ultra-long-term subcutaneous home monitoring of epilepsy-490 days of EEG from nine patients. *Epilepsia.* 2019;60(11):2204-14. PMID: 31608435
2. Djurhuus BD, Viana PF, Ahrens E, et al. Minimally invasive surgery for placement of a subcutaneous EEG implant. *Front Surg.* 2023;10:1304343. PMID: 38026479
3. Milne-Ives M, Duun-Henriksen J, Blaabjerg L, et al. At home EEG monitoring technologies for people with epilepsy and intellectual disabilities: A scoping review. *Seizure.* 2023;110:11-20. PMID: 37295277
4. Rocamora R, Baumgartner C, Novitskaya Y, et al. The spectrum of indications for ultralong-term EEG monitoring. *Seizure.* 2024;121:262-70. PMID: 39326109
5. Rehman M, Higdon LM,Sperling MR. Long-Term Home EEG Recording: Wearable and Implantable Devices. *J Clin Neurophysiol.* 2024;41(3):200-06. PMID: 38436387

6. Duun-Henriksen J, Baud M, Richardson MP, et al. A new era in electroencephalographic monitoring? Subscalp devices for ultra-long-term recordings. *Epilepsia.* 2020;61(9):1805-17. PMID: 32852091
7. 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. PMID: 34497578

CODES

Codes	Number	Description
CPT	0956T	Partial craniectomy, channel creation, and tunneling of electrode for sub-scalp implantation of an electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance
	0957T	Revision of sub-scalp implanted electrode array, receiver, and telemetry unit for electrode, when required, including imaging guidance
	0958T	Removal of sub-scalp implanted electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance
	0959T	Removal or replacement of magnet from coil assembly that is connected to continuous bilateral electroencephalography monitoring system, including imaging guidance
	0960T	Replacement of sub-scalp implanted electrode array, receiver, and telemetry unit with tunneling of electrode for continuous bilateral electroencephalography monitoring system, including imaging guidance
HCPCS	None	

Date of Origin: *May 2025*