NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10086 Software for electroencephalography (EEG) interpretation to support diagnosing epilepsy

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are software for electroencephalography (EEG) interpretation to support diagnosis of epilepsy.

The technologies are assessed for early use. Early use assessment considers HealthTech products that could address a national NHS unmet need. It rapidly assesses products early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

In England and Wales, about 533,000 people, including 112,000 children and young people, have epilepsy (NICE epilepsy guideline [NG217]). According to

the International League Against Epilepsy (ILAE), epilepsy is a disease of the brain defined by any of the following conditions:

- at least 2 unprovoked (or reflex) seizures occurring more than 24 hours apart
- 1 unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next 10 years
- diagnosis of an epilepsy syndrome.

Some people have epilepsy for just a period in their life while others live with it for many years or all their life.

People with epilepsy have repeated bursts of abnormal electrical activity in the brain that lead to epileptic seizures. Usually, a seizure lasts for a few seconds or minutes and then brain activity returns to normal. Epileptic seizures can take different forms. Some involve movements that the person cannot control, such as jerking or twitching, going stiff, or falling to the floor and shaking (generalised seizures). Others involve becoming confused or having unusual sensations (focal seizures). Some people lose awareness while others remain aware of what is happening NICE epilepsy guideline [NG217]).

Epilepsy is a common cause of people attending accident and emergency departments. It is estimated that there are about 100,000 epilepsy-related A&E admissions per year (Epilepsy Research Institute). Epileptic seizures can result in injury and are associated with an increased risk of premature death, for example, because of sudden unexpected death in epilepsy (SUDEP).

3. Current practice

In the NHS, the referral, diagnosis and management of epilepsy and the use of electroencephalogram (EEG) within this care pathway follow:

- British Society for Clinical Neurophysiology (BSCN) and Association of Neurophysiological Scientists (ANS) guidance on referral for neurophysiological testing (2025)

- BSCN guidance on practice of electroencephalography
- NICE epilepsy guideline (NG217)
- NICE epilepsy quality standard (QS175)
- NICE recognition and referral of suspected neurological conditions guideline (NG127)
- NICE transient loss of consciousness ('blackouts') guideline (CG109).

3.1 Referral for a specialist assessment

After a first suspected seizure or when people have a seizure recurrence after a period of remission, NICE epilepsy guideline (NG217) recommends making an urgent referral (for an appointment within 2 weeks) for a specialist assessment. Experts advise that in current practice in the NHS, the referral is usually done after 2 suspected seizures. The specialist assessment is usually by a consultant neurologist or a consultant paediatric neurologist in secondary care.

3.2 Specialist assessment and diagnosis

The specialist assessment aims to find out if the seizure was caused by epilepsy. The assessment includes:

- clinical history, including what happened around and during the seizure, and a physical examination
- assessment and consideration of alternative causes such as cardiac-related conditions (assessment by a 12-lead ECG) or metabolic disturbances
- if these suggest epilepsy, requesting an electroencephalogram (EEG) is considered (if requested after a first seizure, the routine EEG should be done as soon as possible, ideally within 72 hours after the seizure)

Electroencephalogram (EEG)

An EEG, is a recording of the electrical activity of the brain.

NICE epilepsy guideline (NG217) recommends to consider:

- a routine EEG while awake (20 to 40 minutes recording)

If the routine EEG is normal, consider:

- a sleep-deprived EEG while asleep (40 minutes to 1 hour recording)

If the routine and sleep-deprived EEG results are normal, and diagnostic uncertainty persists, consider:

- a longer-term ambulatory EEG (24 to 48 hours recording).

If requested after first seizure, the routine EEG should be done as soon as possible, ideally within 72 hours after the seizure. In current practice, some NHS trusts provide sleep-deprived EEG as the first test.

To record the EEG, a clinical physiologist or scientist places several small electrodes on the head of the person having the test (this takes about 20 minutes). The electrodes are connected to the recording machine and computer, and the EEG is recorded. During the routine EEG or at the beginning of the sleep-deprived EEG, provoking manoeuvres such as deep breathing (hyperventilation) and flashing lights (photic stimulation) are often included. To sleep during the sleep-deprived EEG, people sleep less the night before or are offered melatonin at the hospital before the test. During the test, heart rate, often a video and sometimes muscle activity of the person having the test is also recorded.

The routine and sleep-deprived EEG are done at the hospital. The person having the test will usually either rest in a chair or bed. For the longer-term ambulatory test, people wear a portable EEG machine. They can leave the hospital after the electrodes have been placed and carry on their usual routine during the recording.

Interpreting the EEG

After the test, the EEG recording is reviewed. In shorter tests, the review looks for evidence of epilepsy-related electrical brain activity that may appear between seizures, also called interictal epileptiform discharges or activity, such as spikes and sharp waves. In the longer-term tests, aimed to capture seizures, they also look for evidence of seizures.

First, the clinical physiologist who conducted the test reviews the test recording and writes a factual report describing what happened during the test and an initial interpretation of what the EEG data shows. A consultant clinical neurophysiologist then reads the factual report, reviews the EEG data and writes a clinical report including an interpretation of the test results and clinical conclusions. This report goes back to the neurologist or paediatric neurologist who requested the test for decision making on whether further tests are needed.

The diagnosis of epilepsy is made based on the entire specialist assessment that includes clinical history and assessment of alternative causes of seizures. The EEG can support the diagnosis but not exclude it. Epilepsy can be diagnosed, and the treatment can start without an EEG.

3.3 Further tests

Further investigations to help inform prognosis and to plan management of diagnosed epilepsy may include:

- MRI for people with suspected structural cause of epilepsy (if contraindicated, a CT scan is considered)
- Genetic testing for people with a suspected genetic cause of epilepsy
- Antibody testing for people with a new-onset epilepsy and a suspected autoimmune encephalitis

3.4 Treatment

The main treatment for epilepsy is anti-seizure medicine. These medicines prevent seizures in about 60% to 70% of people with epilepsy. The type of medicine recommended depends on the seizure type, epilepsy syndrome and other factors such as age, sex, plans to have children, other health conditions and medications, and usual or planned activities in life (NICE epilepsy guideline (NG217). Clinical experts estimate that the most prescribed medicines include lamotrigine, levetiracetam, and carbamazepine. Sodium valproate may also be among the most common medications in children.

People can ask for a review of their care if they have concerns, need support or their care needs change. Regular treatment reviews should be provided to groups that are less suited to a self-initiated approach. After a person has been seizure-free for 2 years, (NICE epilepsy guideline (NG217) recommends an individualised assessment to determine if antiseizure medications can be stopped.

For epilepsy with seizures that are not controlled by medication or where other treatment options may be appropriate, other treatment options may include resective epilepsy surgery, vagus nerve stimulation, and ketogenic diet therapies.

4. Unmet need

Conducting and interpreting EEGs needs to be done by specially trained clinicians. The test generates large amounts of results data and interpreting this takes time. The specialist capacity available to conduct and interpret EEGs varies in different parts of the country and so the waiting time for a routine EEG can range from a few weeks to more than 6 months. There is a need for faster access to EEG.

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not done an independent evaluation of these descriptions.

This evaluation includes 2 types of software technologies that help clinicians interpret electroencephalograms (EEGs) recorded using scalp electrodes:

- software that assists reviewing and interpreting EEGs, by automatically detecting and marking interictal spikes, or spikes and seizures in EEG data
- software that assists diagnosing epilepsy, by classifying EEG recordings without visual epileptiform activity based on how supportive they are of epilepsy diagnosis

The software may also provide other information or have other features to assist the review and interpretation.

Epilepsy diagnosis in the NHS most often involves short recordings in an outpatient setting. So software that only detect and mark seizures but not interictal spikes in the EEG data are out of scope.

Sections 5.1 to 5.5 and table 1 briefly describe the 5 included technologies. All the 5 technologies intend to support clinician review and decision making, not replace it. None of the included technologies have restrictions on use based on the type of epilepsy. At the time of writing this scope, all the included technologies were available to the NHS.

5.1 BioEP (Neuronostics)

BioEP is a UKCA-marked (currently class 1 medical device, EU MDR class 2a submission is planned for 2027) software. It analyses digital biomarkers based and classifies the EEG on a 5-point scale from very unsupportive to very supportive of diagnosis of epilepsy. The software is intended to be used for clinically inconclusive EEGs (the neurophysiologist's clinical report concludes that the EEG does not indicate epilepsy). The clinician inputs patient details in the BioEP platform, uploads EEG data via a secure web portal for analysis and downloads the BioEP report. The process from upload to report generation takes less than 10 minutes. If the clinician's initial suspicion of epilepsy is high, and the BioEP score aligns, this might stimulate the clinician to finalise their epilepsy diagnosis. If the initial suspicion is high, but BioEP score is low, the clinician might consider further investigating alternative causes for the seizure. If the initial suspicion is low but the BioEP score is high, the clinician might consider a sleep-deprived or ambulatory EEG. BioEP works with at least 15 minutes of awake, resting-state sections of EEG without seizure or interictal epileptiform activity, ideally recorded with eyes closed. It is suitable for use in people aged 18 or over. Expansion to paediatric population (aged 2 to18) is planned for 2026. The software is not suitable for use with structural brain abnormalities, skull breaches, or intracranial metal or plastic implants. It does not analyse sleep, hyperventilation or photic stimulation

sections, which should be excluded. The software works with any EEG recording platform that produces files in EDF format. The platform includes a mandatory, about 5-minute-long training video that guides users through the process of uploading EEG data and interpreting the report.

5.2 encevis (AIT - Austrian Institute of Technology GmbH)

encevis is a CE-marked (class 2b medical device) software. It has a spike detection module for the automatic marking of areas in the EEG that could correspond to spikes or spike-waves. The seizure detection component automatically detects areas in EEG recordings that may correspond to electroencephalographical recognisable epileptic seizures and displays these markings for review. encevis is suitable for use in people aged 18 or over. The software integrates with existing integrates with existing EEG systems and many different files formats. It supports the DICOM standard for neurophysiology data. The company expects that users would benefit from a brief initial user training focused on system operation, interpretation of automated results, and the use of artefact-reduction tools. Onsite and online training is available.

5.3 NeuroCenter EEG (Clinical Science Systems)

NeuroCenter EEG is a software (currently class 1 medical device, CE-mark class 2a expected in early 2026). The technology is designed to provide detection of interictal epileptiform discharges in routine, sleep-deprived and ambulatory EEG recordings. It highlights EEG segments with a high likelihood of containing IEDs. These flagged segments are displayed in the EEG viewer, where clinicians can review, confirm, or dismiss the marked events. The software works with any EEG recording platform that produces files in EDF+ format. NeuroCenter EEG is suitable for use in people aged 6 years and over. The company expects that users do not need extensive training. Onsite and online training is available.

5.4 NeuroWorks (Natus Medical)

The NeuroWorks EEG software includes autoSCORE, a CE-marked (class 2a medical device) software product. It is intended to assist the user when

reviewing EEG recordings by assessing the probability that the previously acquired sections of EEG recordings contain abnormalities and classifying these into pre-defined types of abnormality. autoSCORE sends this information to the EEG software to indicate where markers indicating abnormality are to be placed in the EEG. The spike detection component of autoSCORE is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes. autoSCORE works with EEG sections from 14 minutes to 4 hours. autoSCORE does not detect or classify seizures. The spike detection component is suitable for use in people aged 3 months or over for EEGs of shorter than 4 hours and people aged 2 years or over for EEGs over 4 hours. The company expects that users familiar with NeuroWorks without autoSCORE do not need extensive training for using NeuroWorks with autoSCORE.

5.5 Persyst 15 (Persyst)

Persyst 15 is a UKCA-marked (class 2a medical device) software. It has a Spike Detection component that is intended to mark sections of the EEG recordings that may correspond to spikes. The Seizure Detection and Seizure Probability component, and the Neonatal Seizure Detection component, are intended to mark sections of EEG recordings that may correspond to electrographic seizures. The Spike Detection -component is suitable for use in people aged 1 month and over. The Seizure Detection and Seizure Probability -component is suitable for use in people aged 18 or over. The Neonatal Seizure Detection component is suitable for use in neonates with conceptional age between 36 and 44 weeks and chronologic age less than 2 weeks. Persyst integrates with existing EEG systems and many different files formats. The company provides user training as part of implementation.

Table 1 Summary of the included technologies

Technology (manufacturer) regulatory status	Software category	Intended age group
BioEP (Neuronostics) UKCA class 1, EU MDR class 2a submission planned for 2027	Assists diagnosing epilepsy, by classifying EEG recordings without visual epileptiform activity based on how supportive they are of epilepsy diagnosis	18 years and over
Encevis (AIT - Austrian Institute of Technology GmbH) CE class 2b	Assists reviewing and interpreting EEGs, by automatically detecting and marking in EEG data: • interictal spikes • seizures	18 years and over
NeuroCenter EEG (Clinical Science Systems) CE class 1, class 2a expected in 2026	Assists reviewing and interpreting EEGs, by automatically detecting and marking in EEG data: • interictal spikes • seizures	6 years and over
NeuroWorks (Natus Medical) CE class 2a	Assists reviewing and interpreting EEGs, by automatically detecting and marking in EEG data: • interictal spikes	• 3 months or over for EEGs of shorter than 4 hours • 2 years or over for EEGs over 4 hours
Persyst 15 (Persyst) UKCA class 2a	Assists reviewing and interpreting EEGs, by automatically detecting and marking in EEG data: • interictal spikes • seizures	• 1 month and over for spike detection • Neonates (conceptional age between 36 and 44 weeks and chronologic age less than 2 weeks) and 18 years or over for seizure detection

5.6 The place of technologies in the care pathway

The software that assists reviewing and interpreting EEGs, by automatically detecting and marking interictal spikes, or spikes and seizures in EEG data, will be assessed for use alongside clinical physiologist's and consultant clinical neurophysiologist's review of the EEG. This type of software may have an effect on the clinician interpretation and report about the EEG. Through the report it may also have an effect on the consultant neurologist's or consultant paediatric neurologist's diagnosis of epilepsy.

The software that assists diagnosing epilepsy, by classifying EEG recordings without visual epileptiform activity based on how supportive they are of epilepsy diagnosis, will be assessed for use as additional information for the specialist assessment for suspected epilepsy together with clinical history, assessment of alternative causes of seizures and the clinical report about the EEG (the EEG does not have visual epileptiform activity). This type of software may have an effect directly on the consultant neurologist's or consultant paediatric neurologist's diagnosis of epilepsy.

5.7 Innovative aspects

The software in this assessment uses AI-derived algorithms to automatically detect and mark epilepsy-related abnormalities on EEG recordings or to calculate digital biomarkers from the EEG recordings that are not visible to the human eye.

6. Comparators

The comparators are:

- Clinician interpretation of EEG without the software that assists reviewing and interpreting EEGs, by automatically detecting and marking interictal spikes, or spikes and seizures in EEG data
- Clinician diagnosis of epilepsy without the software that assists diagnosing epilepsy, by classifying EEG recordings without visual epileptiform activity based on how supportive they are of epilepsy diagnosis.

7. Patient issues and preferences

Getting an epilepsy diagnosis may take time. People without diagnosis may feel worried about not knowing what caused the first seizure, or about having another seizure and the risk of injury and death associated with having an epileptic seizure. Incorrect diagnosis causes harm. While epilepsy diagnosis is not based only on the EEG results, false-positive EEG interpretation can contribute to unnecessary treatment and anxiety, whereas false-negative EEG interpretation can contribute to epilepsy remaining undiagnosed and untreated. People may have concerns over the reliability and accuracy of AI-derived algorithms. But it is important to people that investigations done to diagnose epilepsy provide as much information about the epilepsy and its type as possible to help start or refine the treatment as early as possible.

8. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

8.1 Equality issues related to the condition

- Epilepsy is a disability protected by the Equality Act 2010
- People in the most deprived areas of the UK are more than 30% more likely to have epilepsy than people in the least deprived areas (Wigglesworth et al. 2023, Bush et al. 2024)
- Epilepsy can start at any age but it often starts in young children and people over 50 (NHS conditions: epilepsy)
- 50% of people diagnosed with epilepsy have co-existing health conditions (Epilepsy Research Institute)
- Conditions more common in people with epilepsy than in the general population include for example:
    - Neurodevelopmental conditions such as a learning disability, ADHD, autism or cerebral palsy
    - Dementia (in older people)

- Mental health conditions such as depression and anxiety.

8.2 Equality issues related to the technology

- There is geographical variation in the capacity of epilepsy specialised healthcare professionals such as the clinical neurophysiologists who interpret EEGs – people who live in areas of less availability may have less access or wait longer for services
- EEGs from children may be particularly challenging to interpret because the electrical activity in the brain and so what normal activity looks like changes with the developing brain
- EEGs from older people have different characteristics compared to the EEGs from younger people
- EEGs from people with some neurodevelopmental conditions or neuropsychiatric disorders or having certain medications may be more difficult to interpret because what some electrical brain activity related to these conditions may look like the activity related to epilepsy or the EEG may not show typical epileptiform activity
- People with conditions such as a neurodevelopmental conditions or dementia may find it more challenging to rest during the EEG recording and the movement during the test causes artefacts that may make interpreting the EEG data more challenging
- If the software has been developed and validated in populations in which people with conditions that may make EEG data more challenging to interpret have been underrepresented, it may perform differently in these groups than data suggests.

9. Guidance type

Software for electroencephalography (EEG) interpretation to support diagnosis of epilepsy will be assessed for early use. This is because:

- the assessed technologies have limited or no current use in the NHS
- limited evidence is available for all technologies

- the technologies have the potential to address a high unmet need in the NHS
- the technologies have recent, ongoing or upcoming appropriate regulatory approval for use in the UK.

10. Decision problem

The key decision questions for this assessment are:

- Does using software assisted EEG interpretation to support diagnosing epilepsy have the potential to be clinically and cost-effective use of NHS resources?
- Are there gaps in the evidence base and what are the key gaps?

Table 2: Decision problem

Assessment type	Early use
Population	People having an EEG to support diagnosing epilepsy If the evidence allows, the following subgroups may be considered: • People with conditions that may make it more difficult to interpret the EEG (such as neurodevelopmental conditions, neuropsychiatric disorders, cognitive impairment or medication that could influence the electrical activity in the brain) • Neonates, children, adults
Interventions	Clinician interpretation of EEG using one of the following software: • encevis • NeuroCenter EEG • NeuroWorks • Persyst 15 Clinician diagnosis of epilepsy using the additional information provided about EEGs without visual epileptiform activity by the software: • BioEP The technologies will not be assessed outside of their indicated use.

Comparators	• Clinician interpretation of EEG without the software that assists reviewing and interpreting EEGs, by automatically detecting and marking interictal spikes, or spikes and seizures in EEG data • Clinician diagnosis of epilepsy without the software that assists diagnosing epilepsy, by classifying EEG recordings without visual epileptiform activity based on how supportive they are of epilepsy diagnosis.
Setting	Secondary or tertiary care services
Outcomes and costs (may include but are not limited to)	Intermediate outcomes: • diagnostic accuracy • technical failure rate to analyse EEG • lifetime number of EEGs • number of people with diagnosed epilepsy • clinician EEG review and report turnaround time • impact of software result on clinical decision-making • clinician acceptability and experience • time to diagnosis and treatment Clinical outcomes: • morbidity (including adverse events caused by assessment or treatment) • mortality (including sudden unexpected death in epilepsy [SUDEP]) Patient-reported outcomes: • health-related quality of life • ability to participate in the community (for example having a driver's license or employment) • acceptability, views, experience and satisfaction Costs and resource use: • cost of technology • cost of training • cost of further testing • cost of treatment and management • health service use and cost at different settings
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results.

	The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

11. Other issues for consideration

11.1 Potential implementation issues

Some software may not work with all types of EEG data or file formats, or may add steps to the current workflow. These issues may get solved or improved when further versions of the software are developed. Some of the existing IT infrastructure may need some modifications or upgrading to accommodate new software. NHS England's Digital Technology Assessment Criteria (DTAC) and the early involvement of IT and other relevant stakeholders will help identify needs and feasible solutions.

11.2 Health economic models for epilepsy treatment

NICE epilepsy guideline (NG217) includes health economic models for antiseizure medication and epilepsy surgery treatment. These may be helpful for informing a potential treatment part of any health economic model in this assessment.

11.3 Software development and validation data

The assessment should collate information from the manufacturers on the datasets the software has been trained and validated in.

11.4 Additional innovative aspects and future considerations

Some of the included technologies may also help prioritisation of EEG recordings for review. The effect of using the software to prioritise EEG recordings for review could be explored.

In the future, the technologies may have additional value propositions to address the unmet need. It may be considered that some of the technologies could be used to assist less experienced or specialised clinicians to review EEGs, or to do a first review of the EEG. This could shift the care pathway towards longer EEGs.

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January 2026