Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

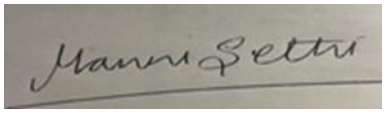
Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices & Keystone First Community HealthChoices	Submission Date: 3/1/2026
Policy Number: CCP.1462	Effective Date: 7/1/2020 Revision Date: 2/1/2026
Policy Name: Embrace 2 watch for seizure detection	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Embrace 2 watch for seizure detection

Clinical Policy ID: CCP.1462

Recent review date: <Recent Review Date>2/2026

Next review date: 6/2027

Policy contains: Embrace 2 watch; epilepsy, seizure monitoring; wristband.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The Embrace 2 watch (Empatica Inc., Cambridge, Massachusetts) for seizure detection is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Traditional methods for seizure diagnosis in people with epilepsy.

Background

Approximately three million American adults and 470,000 children have epilepsy, defined as active epilepsy (self-reported doctor-diagnosed epilepsy and under treatment or with recent seizures within 12 months of interview) or current epilepsy (parent-reported doctor-diagnosed epilepsy and current epilepsy) (Zack, 2017). The national prevalence is 1.2% and nearly three times as high (3.43%) in the Medicaid population (Helmers, 2015).

A Centers for Disease Control and Prevention analysis of National Health Interview Surveys of U.S. adults with self-reported epilepsy revealed that 67% had seen a neurologist or an epilepsy specialist in the past year, and 90% took epilepsy medication. However, only 44% of those taking medication reported controlled seizures. Higher prevalence of active epilepsy and poorer seizure control was found in adults with low family income,

unemployment, and those divorced, separated, or widowed (Tian, 2018). Thus, a need to develop means of better controlling seizures exists.

Embrace automatically transmits data to the Alert app on its paired smartphone, using Bluetooth. The phone and the Embrace device must always be less than 30 feet apart, with no obstructions like walls and doors, making it relatively simple to use at night. It represents an alternative to an electroencephalogram and is more convenient. In the event of an alert signal, the Alert app immediately sends the information to the patient's caregiver.

The U.S. Food and Drug Administration (2018a, 2018b) issued approval to Empatica to market Embrace to adults on February 5, 2018 and to children age 6 and older on December 20, 2018 for use as an adjunct to seizure monitoring in home or healthcare settings during periods of rest. In both approvals, the wrist device senses electrodermal activity and motion that may be associated with tonic clonic seizures in patients with epilepsy or at risk for having epilepsy. Fluctuations in the skin occur from alterations in the brain during a convulsive seizure. The sensors in the wrist device gauge electrodermal activity signals to determine sympathetic nervous system activity related to the amount of sweating that occurs

Findings

The evidence on wearable seizure detection devices supports their utility for detecting generalized tonic-clonic seizures and focal-to-bilateral tonic-clonic seizures, with reported sensitivities generally ranging from 79% to 100% depending on the device, setting, and study methodology. Professional society guidelines provide only conditional recommendations, citing the need for further validation in community settings and for seizure types beyond tonic-clonic events. Systematic reviews consistently demonstrate moderate to high sensitivity for tonic-clonic seizure detection, though false alarm rates vary considerably, and evidence for detection of focal seizures remains limited. Meta-analytic data indicate that wrist-worn devices achieve sensitivity comparable to other wearable surface devices for tonic-clonic seizures, though with somewhat higher false alarm rates. Device performance characteristics have been established primarily in epilepsy monitoring units, with regulatory approval based on controlled inpatient studies, though phase 4 implementation trials in home environments are beginning to demonstrate performance characteristics approaching those observed in clinical settings and meaningful reductions in caregiver burden. User acceptance is generally favorable, particularly for wrist-worn devices, with high retention rates reported in real-world surveys and most users experiencing sensitivity levels consistent with validation studies. Emerging evidence for wearable electroencephalographic detection of absence seizures has demonstrated promising sensitivity for 3-Hz spike-wave discharges in both hospital and home settings. However, evidence demonstrating improvement in clinical outcomes such as injury reduction, quality of life, or mortality remains insufficient, and research priorities include reducing false alarm rates, validating devices for additional seizure types, and conducting longer-term community-based studies.

Guidelines

Professional Society Recommendations

The American Epilepsy Society and the American Academy of Neurology have not issued formal guidelines related to seizure detecting devices, and this absence of guidance from major United States professional organizations reflects the evolving nature of the evidence base and the challenges inherent in developing recommendations for rapidly advancing technology (American Academy of Neurology, 2021; The American Epilepsy Society, 2022). In contrast, the International League Against Epilepsy and the International Federation of Clinical Neurophysiology have issued joint recommendations addressing the clinical use of automated seizure detection wearables (Beniczky, 2021). These recommendations represent the most comprehensive professional society guidance currently available for this device category, though the organizations characterize their recommendations as weak and conditional given the current state of evidence. The disparity between

organizations that have issued guidance and those that have not underscores the lack of consensus regarding the appropriate clinical role for these devices.

Evidence Strength and Clinical Contexts for Use

The International League Against Epilepsy guideline found a high level of evidence for the accuracy of automated detection of generalized tonic-clonic and focal-to-bilateral tonic-clonic seizures, with moderate evidence levels for other seizure types. This distinction in evidence strength across seizure types reflects the fundamental design of most wearable devices, which rely on detection of characteristic motor activity patterns associated with convulsive seizures. The guideline considered the use of clinically validated wearables for detecting these seizure types in situations where significant safety concerns exist, particularly for unsupervised patients, with the aim of enabling rapid intervention within five minutes. The emphasis on unsupervised patients acknowledges the particular vulnerability of individuals who may experience seizures without witnesses present to summon assistance. However, the recommendation is characterized as weak and conditional, reflecting limitations in the available evidence regarding clinical outcomes. At the time of guideline development, the authors identified only one published study of the Embrace device meeting their inclusion criteria, the results of which require evaluation of clinical utility in nonclinical settings (Beniczky, 2021). This observation underscores the gap between device performance demonstrated in controlled epilepsy monitoring unit environments and real-world effectiveness in community settings where patients spend the majority of their time. The conditional nature of the recommendation reflects appropriate caution in the absence of evidence that device use improves patient-centered outcomes such as injury prevention or mortality reduction.

Limitations Acknowledged in Guideline Recommendations

For seizure types other than generalized tonic-clonic and focal-to-bilateral tonic-clonic seizures, the International League Against Epilepsy guideline concluded that current evidence does not support clinical use of these devices, necessitating further research and development. This limitation is significant given that focal seizures without secondary generalization represent a substantial proportion of seizure events experienced by people with epilepsy. Key areas requiring attention identified in the guideline include improving device performance, reducing false alarm rates, conducting robust clinical validation studies, assessing clinical outcomes, and conducting in-field studies to refine technology impact evaluation. The emphasis on false alarm reduction reflects consistent feedback from users and caregivers that frequent false alerts diminish trust in devices and may lead to alert fatigue, potentially compromising the effectiveness of alerts for actual seizure events. Given the rapidly evolving nature of this field, the guideline recommended periodic updates and revisions to incorporate new evidence and advancements (Beniczky, 2021). This acknowledgment of the dynamic evidence landscape recognizes that device capabilities and validation data are accumulating at a pace that may outstrip traditional guideline revision cycles. The recommendation for periodic updates also reflects awareness that current limitations may be addressed by ongoing technological development, making it important to reassess recommendations as new data become available. The guideline thus represents a snapshot of evidence at a particular point in time rather than a definitive and static statement on the role of seizure detection devices.

Systematic Reviews

Device Performance in Controlled Studies

A systematic review that primarily analyzed seven phase three studies with 577 participants tested the accuracy metrics of wearable seizure detection devices including sensitivity and false alarm rates, with the focus on phase three studies ensuring that the analysis captured data from devices that had undergone substantial development and optimization prior to clinical testing (Larsen, 2023). High-level evidence from studies supported the use of wearable devices for automated detection of tonic-clonic seizures when significant safety concerns exist, with a reported sensitivity of 79.4% to 96% and false alarm rates of 0.20 to 1.92 per 24 hours. This range in performance metrics reflects variability across devices, patient populations, and monitoring conditions, and indicates that while

devices consistently achieve high sensitivity, the false alarm experience may differ substantially across clinical contexts. The researchers suggested longer-term usage studies of these devices in real-world community settings, acknowledging that performance characteristics established during relatively brief monitoring periods in clinical environments may not fully predict device behavior during extended use in home and community contexts where movement patterns, environmental factors, and user adherence to device protocols may differ substantially.

User Preferences and Acceptance

A systematic review of 23 observational studies with 3,299 participants examined the preferences and user experiences of people with epilepsy, caregivers, and healthcare workers regarding automated wearable seizure detection devices, with the inclusion of multiple stakeholder perspectives providing a comprehensive view of factors influencing device adoption and sustained use (Sivathamboo, 2022). Accuracy, design, comfort, and cost strongly influenced user acceptance for wearable technology, indicating that technical performance alone does not determine whether devices will be successfully integrated into patients' lives and that practical and aesthetic considerations play substantial roles in adoption decisions. Participants desired real-time detection with a latency of not more than 15 minutes from seizure occurrence, along with at least 90% sensitivity and low false alarm rates, and these user-defined performance thresholds provide benchmarks against which device capabilities can be evaluated from the patient perspective rather than solely from technical or regulatory standpoints. There was a greater acceptance toward wristwatches compared to other device form factors, likely reflecting the social acceptability and familiarity of wristwatch-style devices, which can be worn without drawing attention to the user's medical condition. The authors stressed the need to incorporate user perspectives and experiences in developing wearable devices for seizure detection, particularly in community-based settings. This emphasis on user-centered design recognizes that devices must meet the practical needs and preferences of patients and caregivers to achieve meaningful adoption and sustained use. The findings suggest that device developers should consider not only detection performance but also form factor, comfort, discretion, and cost when designing products intended for long-term patient use. Failure to address these practical considerations may limit adoption even among patients who would otherwise benefit from seizure detection technology.

Real-World Performance and Health Outcomes

Two systematic reviews highlighted the use of wearable devices for health monitoring in community and real-world contexts, specifically focusing on their detection capabilities, user perceptions, and impacts on health outcomes, extending the evidence base beyond controlled clinical environments to address the conditions under which patients actually use these technologies. In the first review, accelerometer-based wearables used for seizure detection achieved sensitivities of at least 80% with a false alarm rate of no more than one per day, although no statistically significant improvements in quality of life were observed (Sasseville, 2024). The absence of demonstrated quality of life benefits despite acceptable detection performance raises important questions about the relationship between device accuracy and meaningful clinical outcomes. Users generally perceived these devices as helpful but voiced concerns regarding false alarms and the visibility of the devices, highlighting the tension between detection sensitivity and specificity as well as the social and psychological dimensions of wearing medical monitoring technology. The second review addressed the real-world accuracy of wearable activity trackers for detecting various medical conditions, finding promising detection rates for coronavirus disease of 2019 and atrial fibrillation, with an area under the curve of 80.2% for COVID-19 and a positive predictive value of 87.4% for atrial fibrillation, albeit with variability across conditions (Singh, 2024). While not specific to epilepsy, these findings situate seizure detection within the broader context of wearable health monitoring and illustrate both the potential and limitations of consumer-grade sensors for medical applications. Collectively, these studies underscore the growing potential of wearable technologies for health condition detection while emphasizing the need for ongoing research to refine their accuracy, minimize user discomfort, and demonstrate tangible benefits in health outcomes. The consistent finding that detection performance does

not automatically translate to improved patient outcomes suggests that implementation factors, alert response protocols, and integration with clinical care may be critical determinants of whether device use produces meaningful benefits.

Meta-analyses

Device Performance Across Sensor Modalities

A systematic review of 28 studies examined the sensitivity and false alarm rates of wearable devices for automated seizure detection, including five studies of wrist-worn devices measuring electrodermal activity, with the inclusion of multiple sensor modalities and device configurations allowing for comparison of detection approaches and identification of relative strengths and weaknesses. Within this review, a meta-analysis of 23 studies with 1,269 participants focused on devices that detect tonic-clonic seizure activity, categorized by device type, and the substantial pooled sample size provides greater statistical precision for estimating device performance parameters than individual studies alone (Naganur, 2022). Compared to wearable surface devices, wrist-worn devices had similar mean sensitivity for detecting tonic-clonic seizures (0.93 versus 0.90) but a higher false alarm rate (2.5 per 24 hours versus 0.96 per 24 hours). This pattern suggests that while wrist-worn devices achieve comparable detection rates, their positioning on a highly mobile body segment may increase susceptibility to movement-related false triggers. The authors recommended further research focusing on reducing false alarm rates, detecting other seizure types and psychogenic nonepileptic seizures, and longer recording in the community. The specific mention of psychogenic nonepileptic seizures acknowledges the clinical importance of distinguishing epileptic from non-epileptic events, a discrimination that current devices are not designed to perform. The recommendation for community-based recording reflects recognition that epilepsy monitoring unit studies, while valuable for establishing detection performance under controlled conditions, do not capture the full range of activities, environments, and circumstances in which patients experience seizures. Addressing these research priorities will be essential for expanding the clinical utility of wearable seizure detection beyond the current limited indications.

Other Evidence Types

Multicenter Validation Studies

A multicenter validation study of multimodal wrist-worn convulsive seizure detectors collected hand-annotated video-electroencephalographic seizure events from 69 patients at six clinical sites, using three different wristbands to record electrodermal activity and accelerometer signals over 5,928 hours of data (Onorati, 2017). The study captured 55 convulsive epileptic seizures, including six focal tonic-clonic seizures and 49 focal-to-bilateral tonic-clonic seizures, from 22 patients. The most efficient classifier, a supervised machine learning algorithm with 22 accelerometer and three electrodermal activity features, yielded a sensitivity of 94.55% and a false alarm rate of 0.2 events per day. All detections occurred before seizure termination, with a median detection latency of 29.3 seconds and a range of 14.8 to 151 seconds, providing reasonable response time for caregiver intervention. Most patients had fewer than one false alarm every four days, with a false alarm rate below their seizure frequency, and notably, no false alarms occurred during resting or sleeping periods. The study also demonstrated the capacity of multimodal systems to characterize seizure physiology beyond mere detection, with automated estimation of seizure motion duration correlating significantly with expert-labeled duration ($r = 0.73$, $p < 0.0001$). Electrodermal activity measurements confirmed the presence of postictal autonomic dysfunction, exhibiting a significant rise in 73% of convulsive seizures, with autonomic dysregulation lasting approximately 13 minutes on average. These findings suggest that wearable devices may provide objective characterization of seizure features relevant to risk stratification, including potential biomarkers associated with sudden unexpected death in epilepsy.

A separate study developed a long-short-term memory deep neural network algorithm for seizure detection using wrist-worn wearable devices, employing transfer learning to adapt a classifier initially trained on intracranial

electroencephalography signals to facilitate classification of non-electroencephalography physiological datasets comprising accelerometry, blood volume pulse, skin electrodermal activity, heart rate, and temperature signals (Nasseri, 2021). For 19 motor seizures from 10 in-hospital patients, the algorithm yielded a mean area under the curve of 0.98, sensitivity of 0.93, and false alarm rate of 2.3 per day. Importantly, the study included ambulatory validation with patients wearing the Empatica E4 device for multiple months while also having an implanted neurostimulator capable of recording intracranial electroencephalography signals, providing independent electrographic seizure confirmation. For eight seizures with probable motor semiology from two ambulatory patients, the classifier achieved a mean area under the curve of 0.97 and a false alarm rate of 2.45 events per day at a sensitivity of 0.9. For all seizure types in the ambulatory setting, the classifier had a mean area under the curve of 0.82 with a sensitivity of 0.47 and a false alarm rate of 7.2 events per day. The significant performance differential between motor and non-motor seizures in ambulatory settings confirms that detection of seizures without prominent motor manifestations remains challenging, though transfer learning approaches may offer methodological advances for addressing limited training data availability.

Manufacturer-Reported Performance

A review by Empatica staff noted that the company's Embrace and E4 wristbands are the first commercially available multimodal wristbands that detect physiological properties of ongoing generalized tonic-clonic seizures, and this characterization reflects the integration of accelerometry and electrodermal activity sensing in a consumer-oriented device form factor (Regalia, 2019). The article found that sensitivity to seizures from these wristbands has steadily ranged from 92% to 100% during their use, while over time, false alarm rates in inpatient settings have fallen from about 2.0 per day to between 0.2 and 1.0 per day. This reported improvement in false alarm rates suggests that algorithm refinement and accumulated training data have enhanced device specificity over successive development cycles. However, the manufacturer source of this review warrants consideration when interpreting the reported performance characteristics, and independent validation remains important for confirming device capabilities.

Regulatory Approval Studies

Regulatory approval of Embrace for adults was based on a multicenter clinical trial of 135 participants with epilepsy admitted for continuous monitoring via video electroencephalography for 272 days, with participants also wearing the Embrace smartwatch simultaneously, allowing direct comparison of device alerts with gold-standard electroencephalographic seizure documentation (U.S. Food and Drug Administration, 2018a). Three independent epileptologists had clinically affirmed 40 seizures in the 135 participants, and after collecting 6,500 hours of data, Embrace detected all 40 (100%) of the generalized tonic-clonic seizures. This perfect sensitivity in the regulatory trial established the device's capability for detecting the seizure type associated with greatest risk of injury and sudden unexpected death in epilepsy. The use of independent expert adjudication of seizure events strengthens confidence in the accuracy of the reference standard against which device performance was measured. Approval for use in pediatric epilepsy was based on 141 participants in an epilepsy monitoring unit, 80 of whom were between the ages of 6 and 21 (U.S. Food and Drug Administration, 2018b). Embrace detected all but one of 54 (98%) of generalized tonic-clonic seizures, and the overall false alarm rates were 0.67% for adults and 1.35% for children. The higher false alarm rate in children may reflect greater movement variability and activity levels in younger patients. These regulatory studies established device performance sufficient for market clearance but were conducted in controlled inpatient environments that may not fully represent conditions of community use.

Prospective Validation Studies

A prospective, nonrandomized, multicenter study evaluated the Embrace device for detecting primary and secondary generalized tonic-clonic seizures in a cohort independent from the original cohort used to develop the device algorithm, and the use of an independent validation cohort addresses concerns about overfitting that can

arise when device performance is evaluated only in populations used to train detection algorithms (Onorati, 2021). The study population comprised 85 pediatric participants aged 6 to 20 years and 67 adults aged 21 to 63 years, and the study setting was in an epilepsy monitoring unit. Device performance complied with regulatory requirements for minimum sensitivity and false alarm rates, confirming that performance observed in development cohorts could be replicated in new patient samples. However, device utility and impact on patient outcomes needs to be established outside of a clinical setting, and this observation acknowledges the fundamental limitation of epilepsy monitoring unit studies, which provide controlled conditions for evaluating detection performance but do not replicate the circumstances under which patients experience the majority of their seizures.

Absence Seizure Detection

A phase 3 clinical trial conducted across four centers validated fully automated absence seizure detection using a wearable electroencephalographic device with a one-channel bipolar recording from dry electrodes embedded in a headband connected to a smartphone (Japaridze, 2023). The study recorded 102 consecutive patients, capturing 364 absence seizures in 39 patients over 309 hours of recording time, with device deficiency of 4.67%. Average sensitivity per patient was 78.83% with a 95% confidence interval of 69.56% to 88.11%, and median sensitivity was 92.90% with an interquartile range of 66.7% to 100%. The average false detection rate was 0.53 per hour with a 95% confidence interval of 0.32 to 0.74, and notably, most patients (64.71%) did not have any false alarms. The median F1 score per patient was 0.823 with an interquartile range of 0.57 to 1, and for the total recording duration, the F1 score was 0.74. As a secondary outcome, the study tested feasibility of automated behavioral testing triggered by seizure detection, correctly documenting nonresponsiveness in 30 absence seizures and responsiveness in six electrographic seizures without clinical correlate. This automated behavioral testing capability represents a potential advance in characterizing the clinical significance of detected events.

A phase 4 home-based study investigated the performance and usability of a wearable two-channel electroencephalographic device for detection of 3-Hz spike-wave discharges in 13 adults with absence epilepsy in their home environment (Swinnen, 2024). Total recording time was 394 hours and 42 minutes, capturing 234 spike-wave discharges in 11 of 13 participants. The algorithm using only electroencephalography achieved sensitivity of 0.86 to 0.87, and visual review of algorithm-labeled segments by experts maintained sensitivity of 0.83 to 0.84 with precision of 0.93 to 0.94 and an F1 score of 0.88 to 0.89. The multimodal algorithm incorporating accelerometer and gyroscope data to discard motion artifacts resulted in similar performance with substantially shorter review time due to fewer false positive labels. The average time with insufficient signal quality was 19% of total recording time, though one-sided signal obscuration allowing readable electroencephalography on the remaining channel occurred in only 9% of recordings. Participants reported the device was comfortable and indicated willingness to wear it on demand of their neurologist for a maximum of one week or with intermediate breaks. These findings demonstrate feasibility of home-based absence seizure monitoring with wearable electroencephalographic devices, though participant tolerance suggests extended continuous monitoring may require protocol modifications.

Home-Based Implementation Studies

A prospective observational study evaluated the real-world performance of the Embrace2 wrist-worn device for timely clinical interventions within an epilepsy monitoring unit, with the study design focusing not only on detection performance but also on the integration of device alerts into clinical workflow and staff response patterns (Jahani, 2026). The study recruited 72 patients (57% female, mean age 39 years, range 19 to 81) between April 2024 and June 2025, with analysis including 373 monitoring days (mean 5.1 days per patient). During the monitoring period, 18 focal-to-bilateral tonic-clonic seizures, one generalized tonic-clonic seizure, and 510 focal seizures occurred. The Embrace2 device detected all 16 focal-to-bilateral tonic-clonic and generalized tonic-clonic seizures that occurred while the device was functioning and worn, but none of the 510 focal seizures,

and this pattern confirms the device's high sensitivity for convulsive seizures and its inability to detect non-convulsive focal events, consistent with its designed detection targets. Alerts successfully reached caregivers in 15 of 16 cases, with one failure due to Wi-Fi disconnection, and seven of the successful alerts occurred during overnight shifts when electroencephalographically trained technicians were typically not on duty. These findings suggest particular value for wearable detection during periods when continuous expert monitoring is unavailable. Twenty-nine false alarms occurred (0.077 per 24 hours), mostly triggered by routine movements such as toothbrushing, and this false alarm rate is notably lower than rates reported in earlier studies and may reflect both algorithm improvements and patient instruction to remove the device during activities likely to trigger false alerts. For detected seizures, the device generated alerts with a median latency of 80 seconds (range 45 to 480 seconds) from electrical onset, and the median latency from the time the focal seizure evolved to bilateral tonic-clonic progression was 25 seconds (range 20 to 90 seconds), with this detection latency relative to the bilateral tonic-clonic phase being clinically relevant because it represents the time available for caregiver response during the most dangerous portion of the seizure. In three of the seven overnight or early-morning cases, intervention was initiated by the shift nurse in response to the generated alert, with a median intervention time of 23 seconds (range 15 to 30 seconds) following alert generation and 90 seconds (range 31 to 103 seconds) following seizure electrical onset. All interventions took place prior to seizure termination, indicating timely clinical response facilitated by the alert system. No injuries, harm, or adverse events occurred during seizure recordings with the wrist-worn device, though practical challenges included the potential for missed alerts when nurses were not carrying their phones; no seizure events were missed for this reason during the study period. The authors concluded that wearable devices show considerable value for seizure detection and triggering timely interventions in epilepsy monitoring unit settings, particularly during off-hours, but successful integration requires robust coordination, reliable infrastructure, and staff engagement.

A phase 4 multicenter prospective video-controlled in-home trial evaluated the performance of a multimodal nocturnal seizure detection device in children with epilepsy living in the family home setting and assessed its impact on caregiver burden (van Westrhenen, 2023). The study included 53 children (55% male, mean age 9.7 years, 68% with learning disability) with at least one weekly nocturnal major motor seizure, and analyzed 2,310 nights totaling 28,173 hours, including 552 major motor seizures. The median detection sensitivity per participant was 100% with a range of 46% to 100%, and the median individual false alarm rate was 0.04 per hour with a range of 0 to 0.53. For tonic-clonic seizures specifically, the overall seizure sensitivity was 94%, and for tonic seizures lasting more than 30 seconds, hyperkinetic seizures, and other major motor seizures, sensitivities varied from 53% to 91%. Nineteen participants did not experience any seizure of interest during the trial period, highlighting the challenge of fluctuating seizure frequency even in populations selected for high baseline rates. Caregiver stress as measured by the Caregiver Strain Index decreased significantly during the intervention period (mean total score 8.0 versus 7.1, $p = 0.032$), whereas caregiver sleep quality and quality of life did not change significantly. The study provides class II evidence that multimodal wearable devices can accurately detect nocturnal major motor seizures in children in a family home setting while demonstrating measurable reduction in caregiver burden.

Patient Preferences and User Experience

A survey of 221 persons with epilepsy showed most were interested in using seizure detectors, indicating substantial patient demand for seizure detection technology despite current limitations in device capabilities and validation (Herrera-Fortin, 2020). Of respondents, 58% considered smartwatches and bracelets or rings as the most acceptable type of detector, and 61% stated they would wear the smartwatch continuously. These preferences for wrist-worn devices and expressed willingness for continuous use suggest that patient acceptance may not represent a major barrier to adoption, provided that devices meet functional expectations for accuracy and reliability. The high level of interest also suggests that efforts to improve device performance

and validation may be well received by the patient population most likely to benefit from seizure detection technology.

A large international survey study evaluated direct user experience with wearable seizure detection devices in the home environment, including 242 users (175 caregivers and 67 persons with epilepsy), with most patients (87.19%) having tonic-clonic seizures (Hadady, 2022). The vast majority of users were overall satisfied with the wearable device (median 6 on a 7-point Likert scale), considered it easy to use, and agreed that device use improved their quality of life. A high retention rate of 84.58% and a long median usage time of 14 months were reported. In the home environment, most users (75.85%) experienced seizure detection sensitivity similar to or exceeding 95%, consistent with performance reported in validation studies conducted in epilepsy monitoring units. The experienced false alarm rate was relatively low, ranging from 0 to 0.43 per day. Due to the alarms, almost one third of persons with epilepsy (30.00%) experienced decrease in the number of seizure-related injuries, and almost two thirds (65.41%) experienced improvement in the accuracy of seizure diaries. The most frequent reasons for stopping device use were too many false alarms (52.94% of discontinuers) and missed seizures (29.41%), while only 5.88% stopped due to the device design being considered stigmatizing. Nonvalidated devices had significantly lower retention rates, overall satisfaction, perceived sensitivity, and improvement in quality of life compared with validated devices (p values ranging from 0.003 to 0.038). These findings demonstrate the feasibility and usefulness of automated seizure detection in the home environment while underscoring the importance of device validation in achieving satisfactory user outcomes.

Digital Health Ecosystem for Epilepsy Management

A narrative review summarized current mobile applications for seizure monitoring and self-management in epilepsy, including seizure diary applications, smartwatch-based monitoring systems, and adherence-focused applications, situating wearable seizure detection within the larger ecosystem of digital health tools available to people with epilepsy (Narodova, 2025). The review noted that validated wearable detectors for generalized tonic-clonic seizures typically report sensitivity in the 80% to 95% range in real-world or simulated real-world studies, alongside variable specificity and false alarm rates, underscoring the need for individualized deployment and calibration. Most applications were found to lack adaptive personalization, language localization, and therapeutically active components, and these limitations constrain the utility of digital tools for diverse patient populations and restrict their role to passive monitoring rather than active intervention support. The review observed that the field is gradually shifting from passive monitoring toward integrated, user-centered platforms that blend monitoring, predictive analytics, and neuromodulation, though comprehensive platforms combining tracking, adherence analytics, and telehealth remain unevenly validated, suggesting that current wearable detection devices represent an intermediate stage in the evolution of digital epilepsy management tools rather than a mature endpoint.

In 2026, we reorganized the findings section and added studies addressing machine learning approaches to multimodal seizure detection (Nasseri, 2021), wearable electroencephalographic detection of absence seizures in hospital and home settings (Japaridze, 2023; Swinnen, 2024), phase 4 implementation trials evaluating device performance and caregiver outcomes in home environments (van Westrhenen, 2023; Jahani, 2026), real-world user experience with validated devices (Hadady, 2022), and the evolving digital health ecosystem for epilepsy self-management (Narodova, 2025). No policy changes were warranted.

References

On January 10, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Wearable Electronic Devices”[MAJR],” “Embrace,” “empatica,” “epilepsy,” “seizure monitoring,” and “wrist devices.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

American Academy of Neurology. Guidelines database. Topic epilepsy. https://www.aan.com/Guidelines/home/ByTopic?topicId=23. Searched December 6, 2022.

American Epilepsy Society. Guidelines. https://aesnet.org/clinical-care/clinical-guidance/guidelines . Published 2022.

Beniczky S, Wiebe S, Jeppesen J, et al. Automated seizure detection using wearable devices: A clinical practice guideline of the International League Against Epilepsy and The International Federation of Clinical Neurophysiology. *Epilepsia.* 2021;62(3):632-646. Doi: 10.1111/epi.16818.

Hadady L, Klivényi P, Fabó D, Beniczky S. Real-world user experience with seizure detection wearable devices in the home environment. *Epilepsia*. 2023;64(Suppl 4):S72-S77. Doi:10.1111/epi.17189.

Helmers SL, Thurman DJ, Durgin TL, Pai AK, Faught E. Descriptive epidemiology of epilepsy in the U.S. population: A different approach. *Epilepsia*. 2015;56(6):942-948. Doi: 10.1111/epi.13001. Epub 2015 Apr 29.

Herrera-Fortin T, Assi EB, Gagnon M-P, Nguyen DK. Seizure detection devices: A survey of needs and preferences of patients and caregivers. *Epilepsy Behav*. 2020;107607. Doi: 10.1016/j.yebeh.2020.107607.

Jahani A, Lazo DAG, Wabi IS, et al. Prospective evaluation of a seizure detection wearable device for timely interventions in an epilepsy monitoring unit. *Epilepsia*. Published online January 7, 2026. Doi:10.1002/epi.70082

Japaridze G, Loeckx D, Buckinx T, et al. Automated detection of absence seizures using a wearable electroencephalographic device: a phase 3 validation study and feasibility of automated behavioral testing. *Epilepsia*. 2023;64(Suppl 4):S40-S46. Doi:10.1111/epi.17200.

Larsen PM, Beniczky S. Non-electroencephalogram-based seizure detection devices: State of the art and future perspectives. *Epilepsy Behav*. 2023;148:109486. Doi: 10.1016/j.yebeh.2023.109486.

Naganur V, Sivathamboo S, Chen Z, et al. Automated seizure detection with noninvasive wearable devices: A systematic review and meta-analysis. *Epilepsia*. Aug 2022;63(8):1930-1941. Doi: 10.1111/epi.17297.

Narodova EA. Digital tools for seizure monitoring and self-management in epilepsy: a narrative review. *J Clin Med*. 2025;14(24):8701. Doi:10.3390/jcm14248701.

Nasseri M, Pal Attia T, Joseph B, et al. Non-invasive wearable seizure detection using long-short-term memory networks with transfer learning. *J Neural Eng*. 2021;18(5):056017. Doi:10.1088/1741-2552/abef8a.

Onorati F, Regalia G, Caborni C, et al. Multicenter clinical assessment of improved wearable multimodal convulsive seizure detectors. *Epilepsia*. 2017;58(11):1870-1879. Doi: 10.1111/epi.13899.

Onorati F, Regalia G, Caborni C, et al. Prospective study of a multimodal convulsive seizure detection wearable system on pediatric and adult patients in the epilepsy monitoring unit. *Front Neurol.* 2021;12:724904. Doi: 10.3389/fneur.2021.724904.

Regalia G, Onorati F, Lai M, Caborni C, Picard RW. Multimodal wrist-worn devices for seizure detection and advancing research: Focus on the Empatica wristbands. *Epilepsy Res*. 2019;153:79-82. Doi: 10.1016/j.eplepsyres.2019.02.007.

Sasseville M, Attisso E, Gagnon MP, et al. Performance, impact and experiences of using wearable devices for seizure detection in community-based settings: a mixed methods systematic review. *Mhealth.* 2024;10:27.. Doi:10.21037/mhealth-24-7.

Singh B, Chastin S, Miatke A, et al. Real-world accuracy of wearable activity trackers for detecting medical conditions: Systematic review and meta-analysis. *JMIR Mhealth Uhealth*. 2024;12:e56972. Doi:10.2196/56972.

Sivathamboo S, Nhu D, Piccenna L, et al. Preferences and user experiences of wearable devices in epilepsy: A systematic review and mixed-methods synthesis. *Neurology*. Sep 27 2022;99(13):e1380-e1392. Doi: 10.1212/wnl.0000000000200794.

Swinnen L, Chatzichristos C, Bhagubai M, et al. Home recording of 3-Hz spike-wave discharges in adults with absence epilepsy using the wearable Sensor Dot. Epilepsia. 2024;65(2):378-388. Doi:10.1111/epi.17839.

Tian N, Boring M, Kobau R, Zack MM, Croft JB. Active epilepsy and seizure control in adults – United States, 2013 and 2015. *MMWR Morb Mortal Wkly Rep*. 2018;67(15):437-442. Doi: 10.15585/mmwr.mm6715a1.

U.S. Food and Drug Administration. Embrace. Section 510(k) premarket notification letter. K172935. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172935.pdf. Published January 26, 2018.(a)

U.S. Food and Drug Administration. Embrace. Section 510(k) premarket notification letter. K181861. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181861.pdf. Published December 20, 2018.(b)

van Westrhenen A, Lazeron RHC, van Dijk JP, Leijten FSS, Thijs RD; Dutch TeleEpilepsy Consortium. Multimodal nocturnal seizure detection in children with epilepsy: a prospective, multicenter, long-term, in-home trial. Epilepsia. 2023;64(8):2137-2152. Doi:10.1111/epi.17654.

Zack MM, Kobau R. National and state estimates of the numbers of adults and children with active epilepsy – United States, 2015. *MMWR Morb Mortal Wkly Rep*. 2017;66(31):721-825. Doi: 10.15585/mmwr.mm6631.a.1.

Policy updates

6/2020: initial review date and clinical policy effective date: 7/2020

2/2021: Policy references updated.

2/2022: Policy references updated.

2/2023: Policy references updated.

2/2024: Policy references updated.

2/2205: Policy references updated.

2/2026: Policy references updated.

Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1462. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code Description
E1399	Durable medical equipment, miscellaneous.
A9279	Monitoring feature/device, stand-alone or integrated. This code includes all accessories and components.