Molina Clinical Policy
Smart Watch Photoplethysmography (PPG) for Detection of Atrial Fibrillation: Policy No. 341

Last Approval: 02/12/2025
Next Review Due By: February 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Atrial fibrillation (AF), the most common sustained cardiac arrhythmia in clinical practice, is characterized by rapid and non-functional contractions of the atria. Ectopic trigger sites in the atria or nearby pulmonary veins generate abnormal electrical impulses, resulting in AF. The causes of AF include an underlying structural cardiac disease, metabolic disorders, endocrine diseases, and specific drugs. AF is a leading cause of stroke, as well as an increased risk of myocardial infarction, chronic kidney disease, dementia, and mortality. It is estimated that AF accounts for 20–30% of all strokes (Pereira et al. 2020).

Photoplethysmography (PPG) is a non-invasive technology that uses optical sensing to measure changes in blood volume with each heartbeat, which is then used to calculate heart rate, infer heart rhythm, and detect rhythm irregularities. Smartphones and smartwatches equipped with optical sensors can thus use PPG to identify the irregular heart rate patterns associated with AF and aid in its detection (Pereira et al. 2020).

Regulatory Status

The FDA classifies PPG analysis software for irregular heart rhythm detection as a Class II (special controls) medical device for over-the-counter use. Multiple wearable devices and mobile applications, such as those from Apple, Fitbit, and Samsung, have their own FDA approved PPG software to provide information for identifying irregular heart rhythms ([2]United States Food and Drug Administration 2024).

For example, in 2022, Apple Inc. received 510(k) clearance for the Atrial Fibrillation History Feature for the Apple Watch and the iPhone Health app, intended for users ≥ 22 years of age diagnosed with AF. The feature analyzes pulse rate data to identify episodes of irregular rhythms suggestive of AF, provides the user with a retrospective estimate of AF burden (the amount of time spent in AF while wearing the Apple Watch), and includes lifestyle data visualizations to help users understand the impact of certain aspects of their lifestyle with AF. It's not intended to provide individual irregular rhythm notifications or replace traditional methods of diagnosis, treatment, or AF monitoring. In 2023, Apple Inc. received 510(k) clearance for the Irregular Heart Rhythm Notification Feature for the Apple Watch, which analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of AF and provides notifications to the user. It's not intended to provide a notification on every episode of irregular rhythm suggestive of AF, and the absence of a notification does not imply disease is not present; rather, the feature is intended to opportunistically surface a notification of possible AF when sufficient data are available for analysis. These data are only captured when the user is stationary. Along with the user's risk factors, the feature can be used to supplement the decision for AF screening. The feature is not intended to replace traditional methods of diagnosis or treatment and has not been tested for or intended for use in people under 22 years of age. It's also not intended for use in individuals previously diagnosed with AF ([1]United States Food and Drug Administration 2024).

COVERAGE POLICY

Wearable devices, including smartwatches (e.g. Apple Watch, Samsung Galaxy Watch) and compatible consumer wrist-worn products (e.g. Fitbit), that use photoplethysmography (PPG) analysis software for the detection of atrial

fibrillation (AF) or other arrhythmias are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Ding et al. (2023) conducted a two-phase randomized control trial (RCT), to evaluate the accuracy, usability, and adherence of a smartwatch-smartphone system for atrial fibrillation (AF) detection among older adults with a history of ischemic stroke or transient ischemic attack. The study included 120 participants, with a mean age of 65 years. Participants were recruited from neurology and cardiology clinics and randomized into intervention and control groups. In phase one, lasting 14 days, participants in the intervention group used the Pulsewatch system, which consisted of a smartwatch and smartphone app, alongside an FDA-cleared ECG patch as the gold standard for comparison, while the control group used only the ECG patch. The Pulsewatch system demonstrated an overall accuracy of 92.9% (95% CI 85.3%-97.4%) for detecting AF when compared to cardiologist-overread ECG data. Sensitivity and specificity were 60% and 95%, respectively, with a positive predicted value of 42.0% and a negative predictive value of 97.4%. Usability of the Pulsewatch system was assessed using the System Usability Scale, with participants reporting a mean score of 62.8 out of 100, indicating moderate usability. Approximately half of the participants found the system highly usable, while 58% indicated a willingness to use the device daily for six months. The study also explored adherence to smartwatch wear time during phase two, a 30-day period in which participants were re-randomized to either continue using the Pulsewatch system or receive no further device intervention. Adherence was defined as wearing the smartwatch for at least one hour daily, and participants wore the device for an average of 21.2 out of 30 days, with a slight decline in usage over time. By day 30, 63% of participants continued wearing the watch, the average daily wear duration remained significant at 11.5 hours. The authors concluded that while smartwatches offer promise for AF detection in older adults at risk for recurrent stroke, strategies to improve adherence and ensure sustained device use are necessary for effective integration into clinical practice.

Systematic Reviews and Meta-Analyses

Tran et al. (2023) performed a systematic review to evaluate the role of wearable devices, particularly those using photoplethysmography PPG technology, in detecting cardiac arrhythmias, particularly AF. Conducted using PRISMA guidelines, the review included 10 studies, including two RCTs (N=1291; N=361), to assess the accuracy, usability, and impact of wearables in clinical settings. Key findings demonstrate that wearable devices exhibit high sensitivity (up to 93%) and specificity (94%) in detecting AF when compared to gold-standard ECG monitoring. One RCT showed increased AF diagnosis and anticoagulation therapy initiation with active wearable monitoring. Another RCT demonstrated that PPG-based devices were particularly effective in detecting persistent AF, with predictive abilities exceeding 91%. The systematic review identified challenges, including variability in adherence, false alarms, alarm fatigue, and potential decline in the patient-physician relationship due to remote monitoring. Additionally, cost remains a barrier, and heterogeneity across study designs limit generalizability. The authors concluded that wearable devices, particularly those using PPG technology are promising for detecting cardiac arrhythmias, including AF, and have potential benefits for stroke prevention and personalized cardiac management, but face challenges related to cost, adherence, and the physician-patient relationship.

Gill et al. (2022) performed a systematic review and meta-analysis to examine the accuracy of smartphone-based PPG in detecting AF compared to standard ECG. The review included 28 studies (10 full-text articles and 18 conference abstracts) with a total of 11,404 participants, of which 2,950 had AF. Key findings showed that smartphone PPG demonstrated high sensitivity (81-100%) and specificity (85-100%) in AF detection. A pooled analysis of 20 comparisons (17 studies with 6,891 participants, 2,299 with AF) showed a sensitivity of 94% (95% CI: 92-95%) and specificity of 97% (95% CI: 96-98%). However, there was substantial heterogeneity across studies and study quality was deemed poor overall as assessed by the QUADAS-2 tool, with significant risks of selection bias (non-randomized

participants), publication bias (small studies skewing results), and lack of transparency regarding algorithms used for PPG signal analysis. As the review primarily addressed diagnostic accuracy rather than clinical outcomes, adverse reactions were not discussed. Most studies utilized commercial smartphone applications and iPhone devices. The review concluded that smartphone PPG holds promise as a non-invasive, patient-led screening tool for AF, but current evidence is insufficient to recommend it in clinical practice due to the small, biased, and low-quality studies. Larger, independent randomized controlled trials are needed to establish its clinical utility and cost-effectiveness.

Elbey et al. (2021) performed a meta-analysis to compare smartwatch technology, single-lead ECG and PPG, to standard monitoring such as ECG, Holter monitor, and patch monitoring for detection of AF. Study selection included all prospective studies that compared smartwatch technology with current monitoring standard and subjects 18 years of age or older. After an initial literature search, nine studies were included in the analysis; case reports, editorial and systematic reviews were excluded. A total of 1559 patients were enrolled, whose mean age was 63.5 years, and of which 39.5% had a history of AF. Mean monitoring time was 75.6 days. In several studies the use of smartwatch technology to detect AF was noted to have overall sensitivity of 90-96%% and specificity of 85-99%. One study noted that with help of algorithms for premature atrial contraction and motion and noise artifact, smartwatches that used PPG were able to detect AF with “higher sensitivity (98.1%), specificity (97.3%) and accuracy (97.5%)”. The authors concluded that smartwatch based single-lead ECG and photoplethysmography appear to be reasonable alternatives for AF monitoring.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Perez et al. (2019) and Raja et al. (2019) reviewed the Apple Heart Study, a large-scale, prospective, single-arm, open-label observational study designed to evaluate the ability of a smartwatch (Apple Watch) using PPG technology to detect irregular pulses suggestive of AF. Conducted between 2017 and 2018, the study enrolled 419,297 participants aged 22 years or older with no prior history or current anticoagulant use. Participants received irregular pulse notifications if the smartwatch algorithm detected ≥ 5 irregular tachograms during periods of rest. Notifications prompted telemedicine consultations, and eligible participants were mailed an ECG patch to wear for up to 7 days. Out of the entire cohort, 2,161 participants (0.52%) received irregular pulse notifications. Of the 450 participants who returned ECG patches, 34% had AF detected on subsequent patch monitoring. Among participants ≥ 65 years, the AF yield was slightly higher at 35%, while it was lower (18%) in participants younger than 40 years. The positive predictive value (PPV) of notifications was 84% (95% CI, 76-92%) and the PPV of individual regular tachograms was 71% (97.5% CI, 69-74%). The study also revealed that 57% of participants who received notifications contacted a healthcare provider within 90 days, with a subset undergoing additional testing or treatment. However, limitations included a younger, healthier cohort (52% were aged 22-39 years) and a lower-than-anticipated return rate of ECG patches, reducing generalizability to older, high-risk populations. The study highlighted the potential of wearable technology for detecting AF while acknowledging the need for further research to clarify its role in clinical practice and address issues such as false positives, follow-up strategies, and cost-effectiveness.

National and Specialty Organizations

The **American Heart Association (AHA)** collaboratively provided the 2023 ACC/AHA/ACCP/HRS *Guideline for the Diagnosis and Management of Atrial Fibrillation*. The guideline notes the use of smartwatches with PPG for AF detection as a promising technology, particularly in population-based screening and high-risk individuals. However, the guideline emphasizes that while these devices demonstrate high sensitivity (97-99%), their specificity (83-94%) remains a concern, leading to potential false positives. Smartwatches are noted to be more reliable for detecting sustained episodes of AF but may miss brief or transient episodes and are susceptible to motion artifact and signal quality issues. The guideline concludes that findings from PPG-based wearables should be clinically confirmed with ECG or other validated monitoring tools before guiding diagnosis or treatment, and further research is needed to clarify their role in clinical practice (Joglar et al. 2024).

The **United States Preventive Services Task Force (USPSTF)** (2022) commissioned a systematic review to update its 2018 recommendation on screening for AF with ECG. The review included adults who were over age 50 and that did not have a history or diagnosis of AF, transient ischemic attack, or stroke. With this review, the USPSTF looked at additional screening tests as well as ECG. It was noted that smartwatches and smartphone apps have ECG or PPG technology to detect irregular heart rhythms but did not specifically address their use. The USPSTF again concludes that the evidence is insufficient to assess the balance of benefits and harms of screening for AF in asymptomatic adults (Tertulian et al. 2022).

The **European Society of Cardiology (ESC)**, in its 2022 position paper, address novel mobile health options for long-term arrythmia monitoring. Monitoring may be performed using ECG-based or non-ECG-based devices. Non-ECG devices such as the smart watch can accurately detect AF, however the patient must be at rest and the device is unable to detect short episodes of AF. Currently there are a number of mobile health devices for long-term ECG monitoring on the market. However, prior to including these devices in clinical practice, the reliability and accuracy of each device must be established. Additional studies are needed to compare mobile health technology with established cardiac monitoring strategies (Dilaveris et al. 2022). This position supplements the ESC's earlier 2020 guidelines, which advises caution in clinical use of these devices, as many are not clinically validated (Hindricks 2020).

The **National Institute for Health and Care Excellence (NICE)** (2021) guideline *Atrial fibrillation: diagnosis and management [NG196]*, note that there is some evidence that new mobile and lead-1 ECG devices are accurate and show promise. However, currently for detection and diagnosis of AF, NICE recommends performing a manual pulse palpation if AF is suspected. A 12-lead ECG should be performed to confirm AF.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

02/12/2025	Policy reviewed. No changes to coverage criteria.
02/14/2024	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References sections. Peer reviewed on January 21, 2024, by a practicing physician board-certified in Cardiovascular Disease.
020/8/2023	Policy reviewed. No changes to position of coverage. Summary of evidence and references updated.
02/09/2022	Policy reviewed, no changes. References updated. New policy template.
02/09/2021	Policy reviewed, no changes. References updated. One new NICE guideline found: Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care. Diagnostics guidance [DG35]. Updated references. Code 0296T was deleted 1/1/2021. Added codes CPT 99457 & 99458.
06/17/2020	Policy reviewed, no changes.
06/19/2019	New policy. IRO Peer Review 03/27/2019. Reviewed by practicing physician board-certified in Internal Medicine, Cardiovascular Disease and Critical Care.

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