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

Last Approval: 2/14//2024
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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) non-invasive heart rhythm measurement technology that uses optical sensing. PPG detects changes in the blood volume of tissue microvasculature in the finger (e.g., with a smartphone camera) or wrist (e.g., with a wearable wristband) using optical sensors. Heart rate (HR) patterns inferred using PPG can be used by smartphones and smartwatches to detect AF.

Regulatory Status

The FDA classifies the Irregular Rhythm Notification Feature (IRNF) 2.0 as “photoplethysmography analysis software for over-the-counter use,” a Class II (Special Controls) device. IRNF 2.0 includes two mobile medical apps: one for the Apple Watch and one for the iPhone. The apps analyze pulse rate data collected by the watch’s PPG sensor to detect episodes of irregular heart rhythms consistent with AF and notify the user.

Apple has received 510(k) clearance for an irregular heart rhythm notification on the Apple Watch. The Apple Watch IRNF is a software-only mobile medical application that is intended to be used with the Apple Watch. The feature analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of AF and provides a notification to the user. The feature is intended for over the counter (OTC) use. It is not intended to provide a notification for every episode of irregular rhythm suggestive of AF, and the absence of a notification does not imply that no disease process is 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 diagnostic or treatment methods.

COVERAGE POLICY

The Apple Watch IRNF (Apple Inc.) and any other Smart Watch device using PPG are **considered experimental, investigational, and unproven** for the detection of AF or other arrhythmias due to insufficient evidence in the peer-reviewed medical literature.

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

There is insufficient published evidence to assess the safety and/or impact on health outcomes of the use of any Smart Watch PPG device or the Apple Watch with Irregular Heart Rhythm Notification Software for the detection of AF or other arrhythmias. There are no randomized controlled trials published in the current literature comparing smart watch devices to standard ambulatory event Holter or loop recorder monitoring. The Pulsewatch study is a randomized study of older stroke survivors using the novel Pulsewatch System (Smartphone App-Smartwatch Dyad} for detection of atrial fibrillation in older adults that compared the system's accuracy with a14-day ECG patch. Several systematic reviews suggest that heart rate measured by smartphone apps performing PPG agrees with a validated method in an adult population in resting sinus rhythm, but that future research with a larger and more diverse study population should be conducted and that the technology should also be tested in more varied clinical situations evoking variations in normal heart rate and during arrhythmias.

Ding et al. (2023) in the Pulsewach study, a multiphase randomized control study, assessed the feasibility of using a smartwatch to monitor for AF in older stroke survivors who were unfamiliar with wearable technology. While mobile apps are available to the public to detect AF, most are designed for younger users. Inclusion criteria was age 50 or older and a history of stroke of transient ischemic attack. Participants were able to sign consent, participate in focus groups, able to use Pulsewatch novel technology (smartwatch and smartphone apps) and return to study site for follow up visits. There were 120 patients recruited for this study. Phase one of the study lasted for fourteen days and looked at accuracy and usability of the smartwatch detection system. This included the experimental intervention group (n=90) that used the test device along with a gold-standard cardiac monitor for comparison to the test device and a control group (n=30) that used only the gold-standard cardiac monitor. Researchers contacted the participants in the intervention group on days 3 and 7 to answer question about the use of the smart devices, troubleshoot and encourage use of the system. After the 14-day window, participants returned for a study visit, completed a questionnaire to address use of the device or devices, and psychosocial elements. Participants in the interventional arm were queried about their experience with the smart devices and apps. In phase two of the study the participants were re-randomized into control and intervention groups at a 1:1 ratio for an additional 30 days to look at adherence to device use. The intervention group used the testing device and a mobile/handheld ECG device for comparison, while the control group did not receive any devices for this phase but were passively monitored. Researchers did not contact participants during this phase of the study. Advice and instruction were provided to participants who called the study hotline during this period. The study collected 9224.38 hours and 182 GB of data from the participants in phases one and two of the study using the smartphone-smartwatch Pulsewatch app. The app demonstrated 93% accuracy over the two-week monitoring period. Half of the patients reported they would want to use the device for AF monitoring after conclusion of the study. Use of the Pulsewatch app and device was high during phase one when participants had contact with researchers but declined over the 30-day phase two monitoring period, when participants were not provided support unless they called into the study hotline. "Use of commercial wearables for AF detection outside of populations who previously owned such devices will require new strategies to improve adherence for effective integration of wearables into clinical settings."

Elbey et al. (2021) performed a meta-analysis to compare smartwatch technology single lead ECG and photoplethysmography to standard monitoring such as ECG, Holter monitor, and patch monitoring for detection of atrial fibrillation. 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, 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 photoplethysmography were able to detect AF with "higher sensitivity (98.1%), specificity (97.3%) and accuracy 97.5%)". The investigators concluded that "Smartwatch based single-lead ECG and photoplethysmography appear to be reasonable alternatives for AF monitoring".

The Apple Heart Study is a large-scale, app-based investigation to identify cardiac arrhythmias using a smartwatch to determine if a fitness band wearable consumer electronic device can passively measure pulse rate from the wrist using PPG. The study (n = 419,297) assessed the capacity of the Apple Watch (Apple Inc, Cupertino, CA) to detect pulse irregularity or variability in order to diagnose atrial fibrillation or atrial flutter. Adults aged 22 and up who had no history of AF or atrial flutter and who were not currently taking anticoagulants were included in the study. The primary objective is to measure the proportion of participants with an irregular pulse detected by the Apple Watch with AF on subsequent ambulatory ECG patch monitoring. The study was conducted virtually, with screening, consent and data collection performed electronically from within an accompanying smartphone app. Study visits were performed by telehealth study physicians via video chat through the app, and ambulatory ECG patches are mailed to the participants. The results of this trial provided initial evidence for the ability of a smartwatch algorithm to identify pulse irregularity and variability which may reflect previously unknown AF. The Apple Heart Study will help provide a foundation for how wearable technology can inform the clinical approach to AF identification and screening (Turakhia et al. 2019). A total 2,161 participants received notifications indicating their heart rates were irregular, and 658 people were mailed an electrocardiogram (ECG) patch when the smartwatch detected AF for more than 30 seconds and concurrent AF on a tachogram. Of the 658 patches, only 450 were returned to the researchers for analysis, and 34% of those 450 presented AF on subsequent ECG patch readings, yielding a 71% positive predictive value (Raja, 2019). The Apple smartwatch study was limited by the large proportion of young participants (52%) ages 22 to 39 who were relatively healthier than the general adult population, with only 21% having hypertension and 5% having diabetes. According to analysts, the Apple smartwatch could be a viable initial diagnostic tool for detecting AF (Perez 2019; Raja 2019).

Participants at the American Heart Association Scientific Sessions discussed the Apple smartwatch study, and the consensus was that the promising technology for detecting AF but still had a number of unanswered questions, including 1) determining cost-effectiveness; 2) the ability to handle large amounts of data; and 3) how to best treat AF prior to the onset of symptoms.

Dorr et al. (2018) in the WATCH AF trial compared diagnosis by a smartwatch-based algorithm using PPG signals to diagnosis by cardiologists using electrocardiography in a group of 508 hospitalized patients. The smartwatch sensitivity (93.7%), specificity (98.2%), and accuracy (96.1%) are all considered high; however, a significant dropout rate (142 of 650) due to poor signal quality is cause for concern.

Koshy et al. (2018) in a small study of 102 hospitalized patients evaluated continuous ECG monitoring with concomitant smart watch using FitBit and Apple Watch over 30 minutes. There were 38,616 HR values recorded across all devices. The sinus rhythm cohort demonstrated significant agreement with both devices and low bias. In atrial arrhythmias, Apple Watch showed a stronger correlation with a lower bias than FB. The strongest agreement was found in both devices for atrial flutter. However, there was significant HR underestimation in AF, with wide agreement limits. The authors concluded that tachycardic episodes recorded at rest on a smart watch could be indicative of an underlying atrial tachyarrhythmia and should be investigated further.

National and Specialty Organizations

The **United States Preventive Services Task Force** (USPSTF) (2022) commissioned a systematic review to update its 2018 recommendation on screening for AF with ECG. This replaces the 2018 recommendation statement. 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 phone apps have ECG or photoplethysmography 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).

European Society of Cardiology, in its 2022 position paper addressed 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).

National Institute for Health and Care Excellence (NICE) guideline titled Atrial fibrillation: diagnosis and management [NG196] (2021) noted that there was some evidence that new mobile and lead-1 ECG devices were accurate and showed 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.

European Society of Cardiology, in its 2020 guidelines for the diagnosis and management of AF diagnosis, indicates mobile health technologies, including smartwatches, as one option for screening. The panel advises "caution in their clinical use, as many are not clinically validated," and adds that studies of watches have a sensitivity range of 97%-99% and a specificity range of 83%-94% (Hindricks 2020).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

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

02/14/2024	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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