

Molina Clinical Policy

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

Last Approval: 2/8/2023

Next Review Due By: February 2024



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 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 "photoplethysmograph 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 AFib 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.

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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. 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.

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.

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 (Dorr, 2019).

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 (Koshy et al. 2018).

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The **United States Preventive Services Task Force (USPSTF)** (2018) guideline concludes that there is insufficient evidence to determine the balance of benefits and harms of screening for AF with ECG in asymptomatic adults.

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%. (Hendricks, 2020).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	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)

HCPCS Codes – N/A

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

2/8/2023	Policy reviewed. No changes to position of coverage. Summary of evidence and references updated.
2/9/2022	Policy reviewed, no changes. References updated. New policy template.
2/9/2021	Policy reviewed, no changes. References updated. One new NICE guideline found: Lead-I ECG devices for detecting symptomatic 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.
6/17/2020	Policy reviewed, no changes.
6/19/2019	New policy. IRO Peer Review 03/27/2019. Reviewed by practicing physician board-certified in Internal Medicine, Cardiovascular Disease and Critical Care.

REFERENCES

Government Agencies

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: Smart watch; Photoplethysmography). No NCD was identified. Available from [CMS](#). Accessed January 2023.
- Food and Drug Administration (FDA). De Novo request for classification of the irregular rhythm notification feature. Published September 11, 2018. Available from [FDA](#).

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Peer Reviewed Publications

1. Dorr M, Nohturfft V, Brasier N, et al. The WATCH AF trial: SmartWATCHes for detection of atrial fibrillation. *JACC Clin Electrophysiol.* 2019;5(2):199-208. Doi: 10.1016/j.jacep.2018.10.006.
2. Koshy AN, Sajeev JK, et al. Smart watches for heart rate assessment in atrial arrhythmias. *Int J Cardiol.* 2018 Sep 1;266:124-127. doi: 10.1016/j.ijcard.2018.02.073. PMID: 29887428.
3. Koshy AN, Sajeev JK. Utility of photoplethysmography for heart rate estimation among inpatients. *Intern Med J.* 2018 May;48(5):587-591. doi: 10.1111/imj.13777.
4. Lu TC, Fu CM, et al. Healthcare applications of smart watches: A systematic review. *Appl Clin Inform.* 2016 Sep 14;7(3):850-69. doi: 10.4338/ACI-2016-03-R-0042.
5. Pereira T, Tran N, Gadhouri K, Pelter MM, Do DH, Lee RJ, et al. Photoplethysmography based atrial fibrillation detection: a review. *NPJ Digit. Med.* 3:eCollection. 2020. doi: 10.1038/s41746-019-0207-9.
6. Raja JM, Elsagr C, Roman S, et al. Apple watch, wearables, and heart rhythm: where do we stand? *Ann Transl Med.* 2019;7(17):417. Doi: 10.21037/atm.2019.06.79.
7. Turakhia MP, Desai M et al. Rationale and design of a large-scale, app-based study to identify cardiac arrhythmias using a smartwatch: The Apple Heart Study. *Am Heart J.* 2019;Jan;207:66-75. doi: 10.1016/j.ahj.2018.09.002.

National and Specialty Organizations

1. Hindricks G, Potpara T, Dagres N. ESC Scientific Document Group. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J.* 2021 Feb 1;42(5):373-498. doi: 10.1093/eurheartj/ehaa612. Erratum in: *Eur Heart J.* 2021 Feb 1;42(5):507. Erratum in: *Eur Heart J.* 2021 Feb 1;42(5):546-547. Erratum in: *Eur Heart J.* 2021 Oct 21;42(40):4194. PMID: 32860505.
2. United States Preventive Services Task Force (USPSTF). Recommendation statement: Screening for atrial fibrillation with electrocardiography. *JAMA.* 2018;320(5):478–484. doi:10.1001/jama.2018.10321.

Evidence Based Reviews and Publications

1. DynaMed. Atrial fibrillation. EBSCO Information Services. Accessed January 9, 2023. Available from [DynaMed](#). Registration and login required.
2. Phang R. New onset atrial fibrillation. Topic 1057 Version 57.0. Topic last updated: Apr 01, 2022. Available from [UpToDate](#). Registration and login required.
3. Madias C. Ambulatory ECG monitoring. Topic 958 Version 39.0. Topic last updated: Nov 29, 2022. Available from [UpToDate](#). Registration and login required.

Other Sources (not cited in policy)

1. De Ridder B, Van Rompaey B, Kampen JK, et al. Smartphone apps using photoplethysmography for heart rate monitoring: Meta-analysis. *JMIR Cardio* 2018;2(1):e4.
2. January CT, et al. 2019 AHA/ACC/HRS* focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the ACC Foundation/AHA Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology* (2019).
3. January CT, et al. 2014 AHA/ACC/HRS* guideline for the management of patients with atrial fibrillation: Executive summary – a report of the ACC/AHA n Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol* 2014;64:2246–80.
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* American Heart Association, American College of Cardiology, Heart Rhythm Society (AHA/ACC/HRS)