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

Last Approval: 2/9/2022
Next Review Due By: February 2023

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) is the most common cardiac arrhythmia and is characterized by the irregular and rapid beating of the atria chambers of the heart. AF occurs when ectopic trigger sites in the atria or nearby pulmonary veins generate aberrant electrical impulses. Causes of AF include an underlying structural heart disease, metabolic disorders, endocrine diseases, and certain medications. AF is a leading cause of stroke and increases the risk of myocardial infarction, chronic kidney disease, dementia, and mortality. It is estimated that 20–30% of all strokes are due to AF (Pereira et al., 2020).

Photoplethysmography (PPG) is a technology that enables non-invasive heart rhythm measurement through optical sensing. PPG uses optical sensors to detect changes in the blood volume of tissue microvasculature in the finger (e.g., using a smartphone camera) or wrist (e.g., using a wearable wristband). Smartphones and smartwatches can detect AF using heart rate patterns inferred using PPG.

Regulatory Status

The FDA classifies 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 on Apple Watch and one on the iPhone. The apps analyze pulse rate data collected by the watch's PPG sensor to identify episodes of irregular heart rhythms consistent with AFib and provide a notification to the user.

Apple 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 on every episode of irregular rhythm suggestive of AF and the absence of a notification is not intended to indicate 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 still. 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.

COVERAGE POLICY

The Apple Watch IRNF (Apple Inc.) and any other Smart Watch device using PPG **is considered experimental, investigational and unproven** for the detection of atrial fibrillation or other arrhythmia 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 for the use of any Smart Watch PPG device or the Apple Watch with Irregular Heart Rhythm Notification Software for the detection of atrial fibrillation or other arrhythmia. 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 suggests 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 conducting a large-scale, app-based investigation to identify cardiac arrhythmias using a smartwatch to identify if a fitness band wearable consumer electronic device can passively measure pulse rate from the wrist using PPG. 419,093 participants were enrolled, the results are not yet published. The primary objective is to measure the proportion of participants with an irregular pulse detected by the Apple Watch (Apple Inc, Cupertino, CA) with AF on subsequent ambulatory ECG patch monitoring. The secondary objectives are to: 1) characterize the concordance of pulse irregularity notification episodes from the Apple Watch with simultaneously recorded ambulatory ECGs; 2) estimate the rate of initial contact with a health care provider within 3 months after notification of pulse irregularity. The study is conducted virtually, with screening, consent and data collection performed electronically from within an accompanying smartphone app. Study visits are 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 will provide 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 small study of 102 hospitalized patients evaluated continuous electrocardiogram (ECG) monitoring with concomitant smart watch using FitBit [FB] and Apple Watch [AW]) over 30 min. The sinus rhythm cohort demonstrated strong agreement for both devices with a low bias. In atrial arrhythmias, AW demonstrated a stronger correlation than FB. Atrial flutter demonstrated strongest agreement in both devices. However, in atrial fib, there was significant heart rate underestimation with wide limits of agreement. Despite heart rate underestimation in atrial fib 98% of values were within +/-10-beats of ECG heart rate. The smart watch demonstrated strong agreement for heart rate estimation in sinus rhythm and atrial flutter but underestimates heart rate in atrial fib. The authors concluded that tachycardic episodes recorded at rest on a smart watch may be suggestive of an underlying atrial tachyarrhythmia and warrant further clinical evaluation. (Koshy et al. 2018).

National and Specialty Organizations

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.

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

2/9/2022 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

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS.
2. Food and Drug Administration (FDA). De Novo request for classification of the irregular rhythm notification feature. Published September 11, 2018. Available from FDA.

Peer Reviewed Publications

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. Lu TC, Fu CM et al. Healthcare applications of smart watches: A systematic review. Appl Clin Inform. 2016 Sep 14;7(3):850-69.
3. Pereira T, Tran N, Gadhoumi 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.
4. Koshy AN, Sajeev JK, et al. Smart watches for heart rate assessment in atrial arrhythmias. Int J Cardiol. 2018;Sep 1;266:124-127.
5. Koshy AN, Sajeev JK. Utility of photoplethysmography for heart rate estimation among inpatients. Intern Med J. 2018 May;48(5):587-591.
6. Lawrie S, Dong Y, et al. Evaluation of a smartwatch-based intervention providing feedback of daily activity within a research-naive stroke ward: a pilot randomised controlled trial. Pilot Feasibility Stud. 2018 Oct 6;4:157.
7. Lu TC, Fu CM, et al. Healthcare applications of smart watches: A systematic review. Appl Clin Inform. 2016 Sep 14;7(3):850-69.
8. Reeder B, David A. Health at hand: A systematic review of smart watch uses for health and wellness. J Biomed Inform. 2016 Oct;63:269-276.
9. Reiffel JA. Mass screening for atrial fibrillation: The hype, the methods, the application. Am J Med. 2019 Jan 15.
10. 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.

National and Specialty Organizations

1. United States Preventive Services Task Force (USPSTF). Recommendation statetment: 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 (record no. T115288). Updated November 30, 2018. Accessed February 1, 2022. Available from DynaMed. Registration and login required.
2. Hayes. Apple watch irregular rhythm notification feature (Apple Inc.) for detection of atrial fibrillation. Available from Hayes. Updated February 2019. Archived March 2020. Registration and login required.
3. Hayes. Patient use of mobile medical applications for detection of cardiac arrhythmias. Available from Hayes. Updated February 2020. Registration and login required.
4. Phang R. New onset atrial fibrillation. Available from UpToDate. Registration and login required.
5. Podrid P. Ambulatory ECG monitoring. Available from UpToDate. Registration and login required.

Other Sources (not cited in policy)

1. Camm JA, et al. 2012 focused update of the European Society of Cardiology (ESC) guidelines for the management of atrial fibrillation: An update of the 2010 ESC Guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm Association, EP Europace. 2012:Oct;(14)10:1385-1413.
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.
4. Kirchof P, et al. 2016 European Society of Cardiology (ESC) guidelines for the management of atrial fibrillation developed in collaboration with EACTS. European Heart Journal, Volume 37, Issue 38, 7 October 2016, 2893–2962.
5. National Institute for Health and Care Excellence (NICE). Atrial fibrillation: Management [CG180]. Published Aug. 2014. Available from NICE.
6. National Institute for Health and Care Excellence (NICE). Lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care [DG35]. Published May 2019. Available from NICE.

* American Heart Association, American College of Cardiology, Heart Rhythm Society (AHA/ACC/HRS)

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*