Subject: Smart Watch Photoplethysmography (PPG) for Detection of Atrial Fibrillation		Original Effective Date: 6/19/19
Policy Number: MCP-341	Revision Date(s):	
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DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Atrial fibrillation (AF) is the most common type of 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 (PV) generate aberrant electrical impulses. AF is associated with a significantly increased risk of death, stroke, declining cognitive function, and development of dementia.

A new way to measure heart rate was developed by utilizing a pulse oximeter applying photoplethysmography (PPG) technology. Two components are essential to create a PPG waveform: a light source to illuminate the subcutaneous tissue and a photodetector to detect the changes in light intensity. Smart watches using PPG technology are under investigation for the detection of irregular heartbeats. One such device is called the Irregular Rhythm Notification Feature from Apple Inc. that was classified through the FDA class II device process and assigned: photoplethysmograph (PPG) analysis software for over-the-counter use. According to the FDA, the Apple Watch Irregular Rhythm Notification Feature (Apple Inc.) 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 Atrial Fibrillation (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.

RECOMMENDATION

The Apple Watch Irregular Rhythm Notification Feature (Apple Inc.) and any other Smart Watch device using Photoplethysmography (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.

SUMMARY OF MEDICAL EVIDENCE [3-15]

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 photoplethysmography (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. [7]

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. [8]

Professional Society Guidelines [3-6]

The USPSTF concludes that there is insufficient evidence to determine the balance of benefits and harms of screening for atrial fibrillation with ECG in asymptomatic adults. Evidence is lacking, and the balance of benefits and harms cannot be determined. [6]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
0296T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording). *(When used for and smart watch device or the Apple Watch Irregular Rhythm Notification Feature)*

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

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Professional Society Guidelines

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Other Resources

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Review/Revision History

6/19/19: New Policy

6/17/20: Policy reviewed, no changes.