Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 2/1/2024
Policy Number: ccp.1453	**Effective Date:** 5/2020 **Revision Date:** January 1, 2024
Policy Name: Smartwatch for detection of atrial fibrillation	

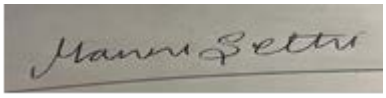
Type of Submission – Check all that apply:

- **New Policy**
- x **Revised Policy***
- **Annual Review – No Revisions**
- **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

Smartwatch for detection of atrial fibrillation

Clinical Policy ID: CCP.1453

Recent review date: 1/2024

Next review date: 5/2025

Policy contains: Atrial fibrillation, cardiac monitoring, heart rate, smart devices, smartwatch.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Smartwatches for detection of atrial fibrillation are investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Ambulatory wearable electrocardiogram devices.
- Holter monitors.
- Cardiac pacemakers.
- Home pulse oximetry.

Background

Atrial fibrillation is the most common type of abnormal heart rhythm, diagnosed by electrocardiogram and occurring in brief episodes or permanently. Common symptoms of light headedness, chest pain/pressure, shortness of breath, and palpitations are due to the inability of the upper heart chambers (left and right atria) to pump oxygenated blood efficiently to the lower chambers (left and right ventricles) which are responsible to supply the rest of the body. Atrial fibrillation leads to increased risk of stroke, heart attack, congestive heart failure, vascular dementia, and other complications (Centers for Disease Control and Prevention, 2022; National Heart, Lung, and Blood Institute, 2019).

By 2030, an estimated 12.1 million Americans will have atrial fibrillation. In 2018-2020, it was the primary cause of over 454,000 U.S. hospitalizations. In 2019, it was mentioned on 183,321 death certificates, and was the underlying cause of death in 26,535 of these (Centers for Disease Control and Prevention, 2022).

In recent years, there has been enormous growth in automated health technology that can be used at home by patients for diagnostic purposes. These devices include the smartphone, monitoring patch, and the medical alert smartwatch, which is worn by the patient but can collect and transmit data to the provider. A 2019 study showed that 21% of U.S. adults wear a smartwatch or wearable fitness tracker (Vogels, 2020). A systematic review of 17 studies documents a sharp rise in analyses of smartwatches starting in 2014 (Reeder, 2016).

Many medical alert smartwatches are able to monitor heart rate. A relatively small proportion can provide a link to support services in the event of a problem, but the proportion is highly likely to grow in the near future (Pickavance, 2019). Improving the ability to monitor heart rate will mean the smartwatch will allow more cases of atrial fibrillation to be detected at home, thus preventing avoidable strokes.

The recent introduction of new smartwatches has prompted manufacturers to reach out to health insurers to increase their usage. In October 2019, Apple created its first agreement with a Medicare (Advantage) provider to subsidize use of their smartwatches. The provider, Devoted Health, will cover up to $150 per year in “wellness bucks for classes, programs, and wearable devices like an Apple Watch.” The Apple Watch 3 costs about $199. Negotiations between Apple and other manufacturers with providers are ongoing (Miller, 2019).

Findings

The U.S. Preventive Services Task Force guideline on screening for atrial fibrillation with electrocardiography could not balance the benefits and risks of screening using established methods and made no mention of using smartwatches for this task (U.S. Preventive Services Task Force, 2018). The Task Force used an evidence review in making its recommendations (Jonas, 2018).

In its guideline for atrial fibrillation diagnosis and management, the European Society of Cardiology included mobile health technologies, including smartwatches, as one option for screening. The panel stated that “caution is needed in their clinical use, as many are not clinically validated.” It also lists studies of watches as having a sensitivity range of 97%-99%, and a specificity range of 83%-94% (Hendricks, 2020)

A systematic review of 24 publications assessed studies involving smartwatches for health care. The two most common focuses of these studies were health monitoring for the elderly (6 of 24), and for patients with Parkinson's disease (5 of 24). The article provided no outcomes data (Lu, 2016).

A literature review of the smartwatch, especially for the detection of atrial fibrillation, emphasizes its potential to assist in cardiovascular diagnosis, and thus prevent disease and mortality. However, the review notes the existence of significant challenges that require improvement, such as lack of outcomes data, false positives, and concerns with data privacy. Collaboration of regulatory bodies and technology companies to support the smartwatch in cardiovascular diagnosis and treatment are also needed (Isakadze, 2020).

A systematic review/meta-analysis of published studies of smartwatches ability to detect atrial fibrillation found a sensitivity of 93% and a specificity of 94% (Prasitlumkum, 2021).

An assessment of the professional literature concludes that there is evidence that long-term cardiac monitoring with new technology, such as a smartwatch, is useful in revealing atrial fibrillation and preventing cryptogenic stroke. Due to small sample sizes and relatively healthy populations, however, further studies are needed (Karmen, 2019).

A systematic review of 22 studies of mobile health devices (mostly smartwatches) to detect atrial fibrillation concluded that better understanding of specific technologies and the most suitable use of mobile health devices can improve diagnosis of the disease (Giebel, 2019).

A large study (n = 419,297) tested the ability of the Apple smartwatch to detect pulse irregularity or variability to identify atrial fibrillation or atrial flutter. The population included adults ages 22 and older without history of atrial fibrillation or atrial flutter, and without current use of anticoagulation. A total of 2,161 subjects were notified of irregular heart rate. Of these, 658 were mailed an electrocardiogram patch after atrial fibrillation of over 30 seconds detected by the smartwatch, with simultaneous atrial fibrillation on a tachogram. Only 450 of the 658 patches were returned to researchers for analysis, and 34% of the 450 had atrial fibrillation on subsequent electrocardiogram patch readings, which represents a positive predictive value of 71% (Raja, 2019).

The Apple smartwatch study was limited by the fact that a large proportion (52%) were young adults from ages 22 to 39. Subjects were relatively healthier than the standard adult population, as only 21% had hypertension and 5% had diabetes. Still, analysts believe that the Apple smartwatch may be a viable initial diagnostic tool for detecting atrial fibrillation (Perez, 2019; Raja, 2019).

The smartwatch app has a much lower positive predictive value for atrial fibrillation in younger adults, specifically 19.6% for ages younger than 55, compared to 76% for ages 60 – 64, 91% for ages 70 – 74, and 96% for ages 85 and older (Yazdi, 2019).

In a study of 187,912 mostly young and middle-aged adults (mean 35 years) who downloaded a smart photoplethysmography screening app and used one of four smartwatches or one wristband to monitor their pulse rhythm in a seven-month period (2018 – 2019), 0.23% (n = 424) received a notification suspecting atrial fibrillation. A total of 227 of 424 were confirmed as having the disorder, and 216 of the 227 entered a program of integrated management of atrial fibrillation using smartwatch technology. Authors concluded that this approach was effective for atrial fibrillation screening (Guo, 2019).

A study of 9,750 participants included 347 with atrial fibrillation and 51 undergoing cardioversion detected with a standard 12-lead electrocardiogram. Over 139 million heart rate measurements were taken using a smartwatch. The ability of the smartwatch to diagnose atrial fibrillation was significant at $P < .001$, with a sensitivity of 98.0% and a specificity of 90.2% (Tison, 2018).

The WATCH AF trial of accuracy of detecting atrial fibrillation in a group of 508 hospitalized patients compared diagnosis by a smartwatch-based algorithm using photoplethysmographic signals to diagnosis by cardiologists using electrocardiography. The smartwatch sensitivity (93.7%), specificity (98.2%), and accuracy (96.1%) are all considered high, although a high dropout rate (142 of 650) due to insufficient signal quality remains a concern (Dorr, 2019).
A systematic review/meta-analysis of 18 studies (16 on atrial fibrillation) on the ability of the smartwatch to detect atrial fibrillation found sensitivity between 94% and 100% and specificity between 96% and 100% in 14 of 18 studies (Nazarian, 2021).

A systematic review of 14 case reports (n = 22) and four cohort studies (n = 854) found relatively high sensitivity of diagnosing arrythmias other than atrial fibrillation (Pay, 2023).

A systematic review of 30 studies of wearable devices in older adults included six with smartwatches. Sensitivity of diagnosing atrial fibrillation ranged from 93% to 98% in four of the studies, with the other two at 68%. Authors state wearable devices offer potential for screening and managing atrial fibrillation in the elderly (Babar, 2023).

References

On October 23, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “atrial fibrillation, cardiac monitoring, heart rate, cardiac dysrhythmias, smart devices, smartwatch, Digital therapeutics, Digital therapeutic applications.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

4/2020: initial review date and clinical policy effective date: 5/2020

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.

1/2024: Policy references updated.