Smartwatch for detection of atrial fibrillation.

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

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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

Other monitors for heart rate that may be worn at home.

Background

Atrial fibrillation is a common type of irregular heart rhythm, marked by rapid heartbeat. The lower chambers do not fill completely or pump enough blood into the body and lungs, which can lead to stroke and other complications (National Heart, Lung, and Blood Institute, 2019). In 2017, between 2.7 and 6.1 million Americans had atrial fibrillation, and about 6% of death certificates that year mentioned the condition (U.S. Centers for Disease Control, 2019).

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 reviews 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 increase in 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).

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) (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, 2019).

A recent assessment of the professional literature concludes that there is evidence that long-term cardiac monitoring with new technology, such as a smartwatch, is useful to reveal atrial fibrillation and prevent 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 was performed. Authors 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 (Turakhia, 2019). 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).

In November 2019, at the American Heart Association Scientific Sessions, participants discussed the Apple smartwatch study and agreed that the promising technology for detecting atrial fibrillation still had several uncertainties to overcome. These included 1) judging cost-effectiveness; 2) ability to handle large quantities of data; and 3) how to best treat atrial fibrillation prior to symptoms appearing (Butterfield, 2020).

The smartwatch app has a much lower positive predictive value 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 (with a mean age of 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 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 study of 100 patients presenting for cardioversion assessed the ability of the Kardia Band (using an Apple Watch) to differentiate sinus rhythm from atrial fibrillation, compared to a 12-lead electrocardiogram. The Apple Watch recordings had 93% sensitivity and 84% specificity from electrocardiograms, and 99% sensitivity and 83% specificity from physician interpretation. The smartwatch can accurately differentiate atrial fibrillation from sinus rhythm (Bumgarner, 2018).

A study of heart rate accuracy compared two wrist-worn smartwatches, namely the Apple Watch Series 3 (20 subjects) and the Fitbit Charge HR (12 subjects), with that of Holter monitoring among ambulatory patients. An analysis of 53,288 heart rate values were included. For both types of smartwatch, strong agreement with Holter monitors were observed in subjects with sinus rhythms. However, heart rate measurements were underestimated in atrial fibrillation patients using smartwatches (Al-Kaisey, 2020).

A study of 40 patients who underwent cardiac surgery each wore two smartwatches (Apple Watch Series 3 and Fitbit Charge HR), to compare the precision of detecting and the accuracy of measuring atrial fibrillation by each. Twenty atrial fibrillation events occurred among the subjects. A significant correlation between the pulse rates and the heart rates during atrial fibrillation was observed only in Apple Watches (Inui, 2020).
A review of 18,608 consecutive R-R-interval measurements recorded simultaneously with photo plethysmography and electrocardiogram in 20 patients, showed that a wearable wristwatch with a sensor, compared with electrocardiogram, distinguished atrial fibrillation from sinus rhythm with a sensitivity of 100% and a specificity of 93.1%. These findings are both highly significant (Hochstadt, 2019).

References

On February 6, 2020, 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,” “smart devices” and “smartwatch.” 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.


**Policy updates**

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