Ambulatory Cardiac Monitoring Devices

Humana®

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Medical Coverage Policy

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Related Medical/Pharmacy Coverage Policies

None

Description

Inpatient cardiac monitoring is not addressed in this medical coverage policy.

Ambulatory cardiac monitoring devices are used by an individual at home to detect and/or manage cardiac arrhythmias and conditions such as cryptogenic (no identifiable cause) stroke. Various devices may be used for monitoring, including, but may not be limited to, continuous recorders (also known as Holter monitors), external loop monitors/recorders (also known as cardiac event monitors/recorders), implantable (insertable) loop monitors/recorders or mobile cardiac outpatient telemetry (also known as mobile cardiac telemetry or real time cardiac monitoring). In addition to symptom frequency, clinical condition and probability of life-threatening arrhythmia, decision-making for the selection of the appropriate ambulatory cardiac monitoring device should also consider diagnostic ability, monitoring and risk stratification accuracy, individual acceptance, availability and provider experience.

Holter and Long-Term Continuous Cardiac Rhythm Monitors/Recorders

The most common cardiac monitoring device is the **Holter monitor** (also known as a continuous recorder). Holter monitors are battery operated portable devices that continuously record the electrical activity of the heart, via leads attached to the chest, during activities of daily living (ADL). A healthcare provider then analyzes the recording to identify arrhythmias. Holter monitors are usually worn for 24 to 48 hours to correlate frequent (daily or more often) symptoms with recordings of symptomatic rhythm events. Other uses include, but may not be limited to, detection of asymptomatic events (eg, nonsustained ventricular tachycardia [NSVT]) for risk stratification of hypertrophic cardiomyopathy or functional assessment of a pacemaker or implantable cardioverter defibrillator (ICD).

Newer versions of rhythm monitors, including patch recorders, may be worn for **long-term continuous cardiac rhythm monitoring** (up to 14 days) to detect arrhythmias that occur less frequently (less than daily). Patch recorders that adhere to the external chest wall without leads or wires continuously record and store rhythm data for 7 – 14 days. The choice of Holter or long-term continuous monitoring device is predicated on the frequency of symptoms or suspected arrhythmia and the degree to which symptoms incapacitate the individual.[6] Examples of long-term continuous cardiac rhythm monitors include, but may not be limited to, Cardea Solo, Carnation Ambulatory Monitor (CAM patch) and Zio XT. The CAM patch is the only long-term monitor that is intended for children weighing at least 22 pounds or adults, while the Cardea Solo and Zio XT are indicated only for adults.

External Loop Monitors/Recorders (Cardiac Event Monitors/Recorders)

External loop monitors are battery operated portable devices that record the electrical activity of the heart during ADL and are worn continuously for up to 30 days. The individual starts the recorder when symptoms begin and turns it off when symptoms end. The device captures and saves a brief period of heart rhythm activity before and after activation. After the individual activates the device, the recording can be transmitted telephonically to a 24-hour attended monitoring center for remote technician review. If the electrocardiogram (ECG) recording is outside preset criteria, a healthcare provider reviews the data and makes individualized clinical decisions. Examples of these devices include, but may not be limited, to Heart 2005A, Heart 2006 and wEvent. In other instances, transmitted ECG data is reviewed later and are considered nonattended.[13]

Implantable (Insertable) Loop Monitors/Recorders

Implantable (insertable) loop recorders are placed directly under the skin in the chest using a local anesthetic. Electrodes in the device sense the heart's activity, so there is no need for external electrodes or leads. When symptoms occur, the individual activates the ECG data recording for analysis by a healthcare provider. The device also has an auto-activation mode to automatically capture and record arrhythmias.

Most recorders can record and store at least 30 minutes of ECG signals during an episode of an arrhythmia. The device is removed when the battery fails, or earlier, if a definitive diagnosis has been established. Examples of these devices with an estimated battery life of 3 years include, but may not be limited to, Assert-IQ, Jot Dx, LUX-Dx and Reveal LINQ implantable cardiac monitoring systems. More recently developed versions of this device have a longer battery life and can be used to monitor and record heart rhythm and rate for 4 or more years. Examples include, but may not be limited to, Biomonitor IIIm and LINQ II implantable cardiac recorders. The LINQ II FDA-approved indications were recently expanded to include an individual 2 years of age or older.

Intracardiac Ischemia Detection Devices

The Guardian System is an implantable cardiac device suggested to measure ST elevation changes and possible impending myocardial infarction (heart attack) via real-time ECG. The system includes an **intracardiac ischemia detection device**, approximately the size of a pacemaker, with a lead placed into the heart, a pager/alerting device and a programming device that monitors the electrical activity of the heart. A healthcare provider programs the device to recognize specific changes in the heart signals which when detected, sends a signal to the pager to alert the individual to seek immediate medical attention. Information from the device can be retrieved for analysis by a healthcare provider. **(Refer to Coverage Limitations section)**

Mobile Cardiac Outpatient Telemetry (Real-Time Cardiac Monitoring)

Mobile cardiac outpatient telemetry (MCOT) records, monitors and transmits an individual's ECG continuously as they go about their normal ADL. A 3-lead sensor transmits each heartbeat to a cellphone sized monitor. If the monitor detects an arrhythmia, it transmits the individual's ECG to the monitoring center using wireless or telephone landline communication technology depending on the individual's location.

Certified cardiovascular technicians analyze the transmissions 24 hours a day. The prescribing healthcare provider selects individualized monitoring thresholds and response parameters. Routine daily telemetry reports are issued to the healthcare provider by email, fax, internet or phone. Examples of MCOT devices include, but may not be limited to, BodyGuardian Mini, MCT 3 Lead, MoMe ARC and Zio AT.

The BioFlux monitors and analyzes ECG data in real time using an ECG algorithm to detect and automatically transmit arrhythmia data to the monitoring center for review. The individual can also activate the device in the presence of any abnormal symptoms. The monitor delivers recorded cardiac activity via smartphone to the server where it is reviewed by a cardiovascular technician and escalated to a healthcare provider when predetermined parameters are met.

The Rhythm Express RX-1, RhythmStar and the TeleSense each function as an external use Holter monitor, event monitor and MCOT depending on the needs of the individual and modality that is ordered by the healthcare provider.

Mobile Patient Management Systems

Mobile patient management systems are monitoring devices designed for detection of cardiac arrhythmias and vital signs. These devices differ from other ECG devices as they may also monitor activity, body fluid status, body temperature, posture and respiratory rate. Examples of such devices are VitalPatch RTM and Vitls/Tego. **(Refer to Coverage Limitations section)**

Self-Monitoring ECG Technologies

Self-monitoring ECG technologies, which may be obtained without a prescription, are generally activated by the touch of the individual's fingers to record and transmit data via a smartphone or watch. These wired or wireless devices are reported to monitor ECG, heart rate and other noncardiac indications and include, but may be not limited, to KardiaMobile Card or Verily Study watch. **(Refer to Coverage Limitations section)**

Electrocardiograph software for over-the-counter use creates, analyzes and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias, such as atrial fibrillation, bradycardia or tachycardia. These devices are not intended to provide a diagnosis. The Apple Watch and Fitbit Sense are

examples of devices that use this technology. Other types of over-the-counter software and related devices are suggested to monitor oxygen saturation, respiratory rate and other body functions. **(Refer to Coverage Limitations section)**

Coverage Determination

Commercial Plan members: requests for repeat studies with like devices within 1 year of the previous study require review by a medical director.

The Rhythm Express RX-1, RhythmStar, TeleSense and similar multi-function monitors are intended for single modality use (Holter OR event recorder OR MCOT modality).

Holter Monitors (93224-93227)
Humana members may be eligible under the Plan for **Holter monitoring** when testing will be completed within 24 to 48 hours **AND** for any of the following indications:

- Assessment of efficacy of medications for arrhythmia treatment; **OR**
- Assessment of the function of a pacemaker or implantable cardioverter defibrillator; **OR**
- Evaluation of cardiac rhythm following surgical or catheter ablation for atrial fibrillation (AF); **OR**
- Frequent (at least once every 24 to 48 hours) episodes of syncope, near-syncope or episodic dizziness without clinical explanation; **OR**
- Hypertrophic or dilated cardiomyopathy; **OR**
- Palpitations; **OR**
- Suspected cardiac arrhythmias; **OR**
- Suspected variant angina; **OR**
- **Pediatric individual** with any of the following indications:
    - Assessment of efficacy of medications for arrhythmia treatment; **OR**
    - Asymptomatic congenital complete atrioventricular (AV) block; **OR**
    - Evaluation of cardiac rhythm after transient AV block associated with heart surgery or catheter ablation; **OR**
    - Evaluation of possible or documented long QT syndrome; **OR**

- Evaluation of rate-responsive or physiological pacing function in a symptomatic individual; **OR**
- Hypertrophic or dilated cardiomyopathy; **OR**
- Palpitations with prior surgery for congenital heart disease and significant residual hemodynamic abnormalities (eg, bradycardia, hypotension); **OR**
- Syncope, near-syncope or dizziness with documented cardiac disease, previously documented arrhythmia or pacemaker dependency; **OR**
- Syncope, near-syncope or sustained palpitations in the absence of a reasonable explanation and where there is no overt clinical evidence of heart disease; **OR**
- Syncope or near-syncope associated with exertion when the cause is not established by other methods

Holter monitoring is generally considered medically necessary no more frequently than twice in a 6 month time period.

Long-Term Continuous Cardiac Rhythm Monitors (93241-93248)

Humana members may be eligible under the Plan for **long-term continuous cardiac rhythm monitors** when the following criteria are met:

- Diagnostic alternative to Holter monitoring when symptoms (eg, syncope, near syncope and/or palpitations) suggestive of a cardiac arrhythmia are infrequent (occur less frequently than once every 48 hours) or unpredictable and require prolonged testing; **OR**
- Evaluation of suspected atrial fibrillation following cryptogenic stroke when the results will be used to guide medical management (eg, anticoagulants); **OR**
- Monitoring within the last 60 days, using either a Holter monitor or hospital telemetry, fails to establish a definite diagnosis because symptoms (eg, syncope, near syncope and/or palpitations) are infrequent (occur less frequently than once every 48 hours) or unpredictable and require prolonged testing; **AND**
- Not utilized in the presence of an external cardiac defibrillator, pacemaker or neurostimulator; **AND**
- Individual is **either**:
  - 18 years of age or older for the Cardea Solo or Zio XT; **OR**
  - Greater than or equal to 22 lbs (10 kg) for the Carnation Ambulatory Monitor (CAM Patch)[12]

Long-term continuous cardiac rhythm monitoring is generally considered medically necessary no more frequently than twice in a 6 month time period.

Mobile Cardiac Outpatient Telemetry (Real-time Cardiac Monitors) (93228, 93229)
Humana members may be eligible under the Plan for **noninvasive mobile cardiac outpatient telemetry (MCOT)/real-time continuous attended cardiac monitor** when the following criteria are met:

- Nondiagnostic monitoring (eg, Holter, long-term cardiac monitor [eg, patch monitor], external loop monitor or hospital telemetry) prior to consideration of the use of MCOT fails to establish a definite diagnosis because symptoms are infrequent (occur less frequently than once every 48 hours) or unpredictable and therefore requires prolonged testing;

  AND any of the following:

  - Recurrent, unexplained syncope; **OR**
  - Suspected paroxysmal atrial fibrillation as the cause of cryptogenic stroke when monitoring will guide medical management with anticoagulants ; **OR**
  - Suspected ventricular arrhythmias that would require immediate intervention

Noninvasive MCOT/real-time continuous attended cardiac monitoring is generally considered medically necessary no more frequently than once in a 6 month time period.

External Loop Monitors/Recorders (Cardiac Event Monitors) (93268, 93270-93272)
Humana members may be eligible under the Plan for **external loop monitors** with 24-hour attended monitoring when the following criteria are met:

- Diagnostic alternative to a Holter monitor when symptoms (eg, syncope, near syncope and/or palpitations) suggestive of a cardiac arrhythmia are infrequent (occur less frequently than once every 48 hours) or unpredictable; **OR**
- Evaluation of Holter monitor results that fail to document a suspected cardiac arrhythmia (eg, suspected AF as cause of cryptogenic stroke)

External loop monitoring is generally considered medically necessary no more frequently than once in a 6 month time period.

Implantable (Insertable) Loop Monitors/Recorders (0650T, 33285, 33286, 93285, 93291, 93298, C1764, E0616)
Humana members may be eligible under the Plan for **implantable** (**insertable) loop monitors/recorders** when **either** of the following criteria are met:

- Atrial fibrillation suspected as the cause of documented cryptogenic stroke[8,41,55] and noninvasive monitoring is contraindicated or nondiagnostic on external monitor; **OR**

- Noninvasive ambulatory monitoring (duration of 48 hours to 30 days) fails to establish a definite diagnosis because symptoms are infrequent (occur less frequently than once every 30 days) or unpredictable, and therefore prolonged testing is necessary[8] for **any** of the following:

    - High risk for arrhythmias due to structural or infiltrative heart disease (eg, cardiac sarcoidosis, congenital heart disease, dilated ischemic or nonischemic cardiomyopathy, hypertrophic cardiomyopathy, valvular aortic stenosis)[8,9]; **OR**

    - Persistent palpitations not captured by previous 30 day external monitor[5,8,45,56]; **OR**

    - Pregnant individual with recurrent syncope[43]; **OR**

    - Recurrent or unexplained infrequent syncope without documented orthostasis or autonomic dysfunction[5,6]; **OR**

    - Suspected ventricular arrhythmia when symptoms occur greater than or equal to every 30 days[5]

Replacement of implantable (insertable) loop monitors/recorders: An individual with an existing implantable (insertable) loop monitor/recorder (ILR) may receive an ILR replacement due to the end of battery life or device malfunction if the ILR continues to be medically necessary.

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **Holter monitors, external loop monitors/recorders, implantable (insertable) loop monitors/recorders, long-term continuous cardiac rhythm monitors or real-time cardiac monitors/MCOT** for any indications other than those listed above. These are considered experimental/ investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Monitoring features/devices, stand-alone or integrated (A9279) are considered integral to the primary device and not separately reimbursable.

Humana members may **NOT** be eligible under the Plan for the following **cardiac monitoring devices**:

- External loop monitors/recorders without 24-hour attended monitoring (93799); **OR**

- Intracardiac ischemia monitoring devices (eg, Guardian System) (0525T-0532T, C1833, G2066); **OR**

- Mobile patient management systems (eg, VitalPatch, Vitls/Tego) (93225, 93246, 99453, 99454, 99457, 99458)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **self-monitoring** or **over-the-counter ECG technologies** for any indication. Although they may be prescribed by a health care practitioner, **self-monitoring or over-the-counter (OTC) ECG technologies** are also available without a prescription and may be obtained over the counter (OTC) and are therefore generally excluded in the certificate. In the absence of a certificate exclusion for OTC items, **self-monitoring** or **OTC ECG technologies** are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming	
33286	Removal, subcutaneous cardiac rhythm monitor	
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional	
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)	**Not Covered if used to report any device outlined in Coverage Limitations section**
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report	
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional	

93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional	
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional	
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	**Not Covered if used to report any device outlined in Coverage Limitations section**
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	**Not Covered if used to report any device outlined in Coverage Limitations section**
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	**Not Covered if used to report any device outlined in Coverage Limitations section**

93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	**Not Covered if used to report any device outlined in Coverage Limitations section**
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional	
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)	
93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis	**Not Covered if used to report any device outlined in Coverage Limitations section**
93272	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; review and interpretation by a physician or other qualified health care professional	
93285	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; subcutaneous cardiac rhythm monitor system	
93290	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors	

93291	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; subcutaneous cardiac rhythm monitor system, including heart rhythm derived data analysis	
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	
93799	Unlisted cardiovascular service or procedure	**Not Covered if used to report any device outlined in Coverage Limitations section**
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	**Not Covered if used to report any device outlined in Coverage Limitations section**
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	**Not Covered if used to report any device outlined in Coverage Limitations section**
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	**Not Covered if used to report any device outlined in Coverage Limitations section**
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)	**Not Covered if used to report any device outlined in Coverage Limitations section**
CPT® Category III Code(s)	**Description**	**Comments**

0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	**Not Covered**
0526T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only	**Not Covered**
0527T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only	**Not Covered**
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	**Not Covered**
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	**Not Covered**
0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)	**Not Covered**
0531T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; electrode only	**Not Covered**
0532T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; implantable monitor only	**Not Covered**
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional	
HCPCS Code(s)	**Description**	**Comments**
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified	**Monitoring features/devices, stand-alone or integrated are considered integral to the primary device and not separately reimbursable**
C1764	Event recorder, cardiac (implantable)	**Not Covered if used to report any device outlined in Coverage Limitations section**

C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	**Not Covered**
E0616	Implantable cardiac event recorder with memory, activator, and programmer	
E1399	Durable medical equipment, miscellaneous	**Not Covered if used to report any device outlined in Coverage Limitations section**
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	**Not Covered if used to report any device outlined in Coverage Limitations section** **Deleted Code Effective 12/31/2023**

References

1. American Academy of Neurology (AAN). Summary of evidence-based guideline update: prevention of stroke in nonvalvular atrial fibrillation. https://www.aan.com. Published April 22, 2014. Updated October 22, 2022.

2. American College of Cardiology (ACC). 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities. https://www.acc.org. Published January 22, 2013.

3. American College of Cardiology (ACC). 2015 ACC/AHA/HRS guideline for the management of adult patients with supraventricular tachycardia. https://www.acc.org. Published April 5, 2016.

4. American College of Cardiology (ACC). 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope. https://www.acc.org. Published August 1, 2017.

5. American College of Cardiology (ACC). 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. https://www.acc.org. Published October 2, 2018.

6. American College of Cardiology (ACC). 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay. https://www.acc.org. Published August 20, 2019.

7. American College of Cardiology (ACC). 2018 AHA/ACC guideline for the management of adults with congenital heart disease. https://www.acc.org. Published April 2, 2019.

8. American College of Cardiology (ACC). 2023 ACC/AHA/ACCP/HRS guideline for the diagnosis and management of atrial fibrillation. https://www.acc.org. Published January 2, 2024.

9. American College of Cardiology (ACC). 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR guideline for the management of hypertrophic cardiomyopathy. https://www.acc.org. Published June 11, 2024.

10. American Heart Association (AHA). AHA/ASA Scientific Statement. Prevention of stroke in patients with silent cerebrovascular disease. https://www.heart.org. Published February 2017.

11. American Heart Association (AHA). Guidelines for the prevention of stroke in patients with stroke and transient ischemic attack. https://www.heart.org. Published July 2014.

12. Bardy Diagnostics. Carnation Ambulatory Monitor (CAM) instructions for use. https://www.bardydx.com. Published August 2020.

13. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Electrocardiographic services (20.15). https://www.cms.gov. Published August 26, 2004.

14. ClinicalKey. Calkins H, Everett TH, Chen PS. Hypotension and syncope. In: Libby P, Bonow RO, Mann DL, Tomaselli GF, Bhatt DL, Solomon SD. *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine.* 12th ed. Elsevier; 2022:1387-1397. https://www.clinicalkey.com.

15. ClinicalKey. Goldberger AL, Goldberger ZD, Shvilkin A. Electrocardiogram leads. In: Goldberger AL, Goldberger ZD, Shvilkin A. *Goldberger's Clinical Electrocardiography*. 10th ed. Elsevier; 2024:22-32. https://www.clinicalkey.com.

16. ClinicalKey. Goldberger JJ, Albert CM, Myerburg RJ. Cardiac arrest and sudden cardiac death. In: Libby P, Bonow RO, Mann DL, Tomaselli GF, Bhatt DL, Solomon SD. *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine.* 12th ed. Elsevier; 2022:1349-1386. https://www.clinicalkey.com.

17. ClinicalKey. Olgin JE. Approach to the patient with suspected arrhythmia. In: Golman L, Schafer AI. *Goldman-Cecil Medicine*. 27th ed. Elsevier; 2024:303-312.e1. https://www.clinicalkey.com.

18. ClinicalKey. Richardson TD, Stevenson WG. Assessment of the patient with a cardiac arrhythmia. In: Jalife J, Stevenson WG. *Zipes and Jalife's Cardiac Electrophysiology: From Cell to Bedside*. 8th ed. Elsevier; 2022:693-699. https://www.clinicalkey.com.

19. ClinicalKey. Turahkia MP. Wearable devices in cardiovascular medicine. In: Libby P, Bonow RO, Mann DL, Tomaselli GF, Bhatt DL, Solomon SD. *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine.* 12th ed. Elsevier; 2022:117-122. https://www.clinicalkey.com.

20. De Angelis MV, Di Stefano V, Franciotti R, et al. Cryptogenic stroke and atrial fibrillation in a real-world population: the role of insertable cardiac monitors. *Sci Rep.* 2020;10:3230.

21. ECRI Institute. Clinical Evidence Assessment. AngelMed Guardian System (Angel Medical Systems, Inc.) for monitoring patients at high risk of acute coronary syndrome. https://www.ecri.org. Published January 17, 2020. Updated February 23, 2022.

22. ECRI Institute. Clinical Evidence Assessment. BioTel MCOT (BioTelemetry, Inc.) for diagnosing and managing cardiac arrhythmias. https://www.ecri.org. Published March 18, 2019. Updated September 1, 2022.

23. ECRI Institute. Clinical Evidence Assessment. BodyGuardian Heart (Preventice Solutions, Inc.) for aiding diagnosis of cardiac arrhythmias. https://www.ecri.org. Published September 23, 2020. Updated May 5, 2022.

24. ECRI Institute. Clinical Evidence Assessment. Carnation ambulatory monitor (Bardy Diagnostics, Inc.) for cardiac arrhythmias. https://www.ecri.org. Published June 25, 2018. Updated January 28, 2022.

25. ECRI Institute. Clinical Evidence Assessment. LUX-Dx insertable cardiac monitor (Boston Scientific Corp.) for patients at risk of cardiac arrhythmia. https://www.ecri.org. Published June 1, 2021.

26. ECRI Institute. Clinical Evidence Assessment. MoMe Kardia (InfoBionic) for aiding diagnosis of cardiac arrhythmias. https://www.ecri.org. Published May 9, 2022.

27. ECRI Institute. Clinical Evidence Assessment. Outpatient cardiac telemetry monitors for diagnosing and managing cardiac arrhythmias. https://www.ecri.org. Published March 25, 2019. Updated January 31, 2022.

28. ECRI Institute. Clinical Evidence Assessment. Overview of selected ambulatory cardiac monitoring systems for aiding diagnosis of cardiac arrhythmias. https://www.ecri.org. Published September 1, 2022.

29. ECRI Institute. Clinical Evidence Assessment. Reveal LINQ II insertable cardiac monitor (Medtronic plc.) for adults at risk of cardiac arrhythmia. https://www.ecri.org. Published October 1, 2018. Updated March 15, 2023.

30. ECRI Institute. Clinical Evidence Assessment. Reveal LINQ II insertable cardiac monitor (Medtronic plc.) for children at risk of cardiac arrhythmia. https://www.ecri.org. Published October 1, 2018. Updated March 17, 2023.

31. ECRI Institute. Clinical Evidence Assessment. RhythmStar (Rhythmedix) for aiding diagnosis of cardiac arrhythmias. https://www.ecri.org. Published August 8, 2022.

32. ECRI Institute. Clinical Evidence Assessment. VitalPatch Biosensor (VitalConnect, Inc.) for continuous vital signs monitoring in patients with COVID-19. https://www.ecri.org. Published May 8, 2018. Updated May 21, 2020.

33. ECRI Institute. Clinical Evidence Assessment. Zio Patch (iRhythm Technologies, Inc.) for aiding diagnosis of cardiac arrhythmias. https://www.ecri.org. Published August 22, 2013. Updated May 5, 2022.

34. Hayes, Inc. Evidence Analysis Research Brief. The AngelMed Guardian System for management of acute coronary syndrome. https://evidence.hayesinc.com. Published January 10, 2022.

35. Hayes, Inc. Evolving Evidence Review. Clinical utility of mobile medical applications for detection of cardiac arrhythmia episodes. https://evidence.hayesinc.com. Published June 8, 2021. Updated July 12, 2024.

36. Hayes, Inc. Evolving Evidence Review. Zio Monitors (iRhythm) for heart rhythm monitoring in pediatrics. https://evidence.hayesinc.com. Published September 21, 2022. Updated July 28, 2023.

37. Hayes, Inc. Health Technology Brief. Implantable cardiac loop recorders for detection of atrial fibrillation following cryptogenic stroke. https://evidence.hayesinc.com. Published June 15, 2017. Updated July 18, 2019.

38. Hayes, Inc. Health Technology Brief. Zio Patch (iRhythm Technologies, Inc.) long-term ambulatory cardiac rhythm monitoring. https://evidence.hayesinc.com. Published February 7, 2019. Updated April 30, 2021.

39. Hayes, Inc. Medical Technology Directory. Implantable cardiac loop recorders for diagnosis and management of syncope in adults. https://evidence.hayesinc.com. Published March 10, 2016. Updated June 6, 2020.

40. Heart Rhythm Society (HRS). 2017 HRS/EHRA/SCAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. https://www.hrsonline.org. Published October 2017.

41. Heart Rhythm Society (HRS). 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. https://www.hrsonline.org. Published July 2017.

42. Heart Rhythm Society (HRS). 2020 APHRS/HRS expert consensus statement on the investigation of decedents with sudden unexplained death and patients with sudden cardiac arrest, and of their families. https://www.hrsonline.org. Published January 2021.

43. Heart Rhythm Society (HRS). 2023 HRS expert consensus statement on the management of arrhythmias during pregnancy. https://www.hrsonline.org. Published October 2023.

44. Heart Rhythm Society (HRS). Position Paper. 2021 ISHNE/HRS/EHRA/APHRS collaborative statement on mHealth in arrhythmia management: digital medical tools for heart rhythm professionals. https://www.hrsonline.org. Published February 2021..

45. Nadkarni A, Devhun J, Jamal SM, et al. Subcutaneous cardiac rhythm monitors: state of the art review. *Expert Rev Med Devices.* 2021;18(7):587-596.

46. UpToDate, Inc. Ambulatory ECG monitoring. https://www.uptodate.com. Updated May 2024.

47. UpToDate, Inc. Arrhythmogenic right ventricular cardiomyopathy: diagnostic evaluation and diagnosis. https://www.uptodate.com. Updated May 16, 2024.

48. UpToDate, Inc. Athletes with arrhythmias: clinical manifestations and diagnostic evaluation. https://www.uptodate.com. Updated May 2024.

49. UpToDate, Inc. Atrial arrhythmias (including AV block) in congenital heart disease. https://www.uptodate.com. Updated May 2024.

50. UpToDate, Inc. Atrial fibrillation: overview and management of new-onset atrial fibrillation. https://www.uptodate.com. Updated May 2024.

51. UpToDate, Inc. Bradycardia in children. https://www.uptodate.com. Updated May 2024.

52. UpToDate, Inc. Cardiac evaluation of the survivor of sudden cardiac arrest. https://www.uptodate.com. Updated May 2024.

53. UpToDate, Inc. Cardiac manifestations of systemic sclerosis (scleroderma). https://www.uptodate.com. Updated May 2024.

54. UpToDate, Inc. Clinical manifestations and diagnosis of cardiac sarcoidosis. https://www.uptodate.com. Updated May 2024.

55. UpToDate, Inc. Cryptogenic stroke and embolic stroke of undetermined source (ESUS). https://www.uptodate.com. Updated May 2024.

56. UpToDate, Inc. Evaluation of palpitations in adults. https://www.uptodate.com. Updated May 2024.

57. UpToDate, Inc. Incidence of and risk stratification for sudden cardiac death after myocardial infarction. https://www.uptodate.com. Updated May 2024.

58. UpToDate, Inc. Invasive cardiac electrophysiology studies. https://www.uptodate.com. Updated May 2024.

59. UpToDate, Inc. Irregular heart rhythm (arrhythmias) in children. https://www.uptodate.com. Updated May 2024.

60. UpToDate, Inc. Microvascular angina: angina pectoris with normal coronary arteries. https://www.uptodate.com. Updated May 2024.

61. UpToDate, Inc. Overview of the evaluation of stroke. https://www.uptodate.com. Updated May 2024.

62. UpToDate, Inc. Sinus node dysfunction: clinical manifestations, diagnosis and evaluation. https://www.uptodate.com. Updated May 2024.

63. UpToDate, Inc. Supraventricular premature beats. https://www.uptodate.com. Updated May 2024.

64. UpToDate, Inc. Syncope in adults: risk assessment and additional diagnostic evaluation. https://www.uptodate.com. Updated May 2024.

65. UpToDate, Inc. Vasospastic angina. https://www.uptodate.com. Updated May 2024.

66. US Food & Drug Administration (FDA). 510(k) summary: Assert-IQ Insertable Cardiac Monitor. https://www.fda.gov. Published May 17, 2023.

67. US Food & Drug Administration (FDA). 510(k) summary: BioFlux Device. https://www.fda.gov. Published December 15, 2017. Accessed January 8, 2018.

68. US Food & Drug Administration (FDA). 510(k) summary: BioMonitor III/IIIm. https://www.fda.org. Published December 8, 2020. Accessed June 3, 2021.

69. US Food & Drug Administration (FDA). 510(k) summary: Carnation ambulatory monitor. https://www.fda.gov. Published December 22, 2014. Accessed February 13, 2019.

70. US Food & Drug Administration (FDA). 510(k) summary: CardeaScreen. https://www.fda.gov. Published February 5, 2013.

71. US Food & Drug Administration (FDA). 510(k) summary: Heart 2006. https://www.fda.gov. Published October 3, 2003. Accessed April 27, 2022.

72. US Food & Drug Administration (FDA). 510(k) summary: Jot Dx insertable cardiac monitor. https://www.fda.gov. Published August 12, 2021. Accessed April 27, 2022.

73. US Food & Drug Administration (FDA). 510(k) summary: LifeWatch mobile cardiac telemetry 3 lead. https://www.fda.gov. Published October 3, 2003. Accessed April 27, 2022.

74. US Food & Drug Administration (FDA). 510(k) summary: LINQ II Insertable Cardiac Monitor. https://www.fda.gov. Published August 25, 2022. Accessed September 21, 2022.

75. US Food & Drug Administration (FDA). 510(k) summary: LUX-DX Insertable Cardiac Monitor. https://www.fda.gov. Published June 26, 2020. Accessed April 27, 2022.

76. US Food & Drug Administration (FDA). 510(k) summary: MoMe ARC wireless ambulatory ECG monitoring and detection system. https://www.fda.gov. Published October 6, 2023.

77. US Food & Drug Administration (FDA). 510(k) summary: Reveal LINQ Insertable Cardiac Monitor. https://www.fda.gov. Published July 22, 2021. Accessed August 11, 2021.

78. US Food & Drug Administration (FDA). 510(k) summary: RhythmStar System. https://www.fda.gov. Published August 5, 2014. Accessed February 21, 2023.

79. US Food & Drug Administration (FDA). 510(k) summary: RX-1 Rhythm Express remote cardiac monitoring system. https://www.fda.gov. Published September 2, 2020. Accessed February 22, 2023.

80. US Food & Drug Administration (FDA). 510(k) summary: TeleSense. https://www.fda.gov. Published December 12, 2014. Accessed December 30, 2016.

81. US Food & Drug Administration (FDA). 510(k) summary: Zio ECG Utilization Service (ZEUS) System. https://www.fda.gov. Published July 23, 2019. Accessed May 2, 2022.

82. Zangiabadian M, Soltani K, Gholinejad Y, et al. Predictors of pacemaker requirement in patients with implantable loop recorder and unexplained syncope; a systematic review and meta-analysis. Clin Cardiol. 2024;47(2):e24221.

Change Summary

- 07/25/2024 Annual Review, Coverage Change.