

Patch-Type Cardiac Monitor

ACG: A-0734 (AC)

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Ambulatory Care
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Clinical Indications

- Patch-type cardiac monitor may be indicated when **ALL** of the following are present(1)(2)(3)(4)(5):
 - Need for ambulatory cardiac monitoring, as indicated by **1 or more** of the following(11):
 - Bradycardia or cardiac conduction disorder, known or suspected(12)(13)[N](#)
 - Palpitations(14)(15)(16)[N](#)
 - Paroxysmal atrial fibrillation, known or suspected(19)(20)(21)(22)(23)(24)[N](#)
 - Presyncope, syncope, or other transient loss of consciousness(13)(17)(27)(28)[N](#)
 - Symptom frequency as indicated by **1 or more** of the following(2):
 - Episode expected to occur less frequently than every 48 hours(16)(29)
 - Episode expected to occur within 48 hours, and Holter monitor has failed to identify suspected clinically significant arrhythmia

Alternatives

- Alternatives include(12)(15)(20)(30)(31):

- o Ambulatory cardiovascular telemetry monitor(32)
- o Holter monitor. See Holter Monitor [AC](#) for further information.
- o Loop recorder, implantable. See Loop Recorder (Cardiac Event Monitor), Implantable [AC](#) for further information.
- o Loop recorder, non-implantable. See Loop Recorder (Cardiac Event Monitor), Non-Implantable [AC](#) for further information.

Evidence Summary

Background

The patch-type cardiac monitor is a long-term external cardiac monitoring device designed to improve diagnostic yield when evaluating suspected symptomatic arrhythmias by attempting to overcome the structural limitations of the Holter monitor.(2)(6) **(EG 2)** The patch-type cardiac monitor, which can monitor and record ECG data on an ambulatory basis for up to 14 days, includes an event trigger that places a digital time stamp on the recorded ECG rhythm when activated by the patient during a symptomatic event. At the end of the monitoring period, the patient removes the device and mails it to a facility for analysis. While the Holter monitor is attached by external leads and wires to a recording device, the patch-type cardiac monitor is contained in a small water-resistant adhesive patch that is placed on the chest wall by the patient and can be worn continuously, even while bathing.(3)(7)(8)(9) **(EG 2)** Review articles note that the patch-type cardiac monitor is easier to use than a Holter monitor (and some event recorders), which may lead to increased device wear time and diagnostic yield.(6)(10) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 25 published peer reviewed articles and 4 specialty society or other evidence-based guidelines.

For bradycardia or cardiac conduction disorder, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline states that prolonged ambulatory electrocardiographic monitoring, such as that provided by patch-type cardiac monitors, is appropriate for patients with known or suspected bradycardia or conduction disorders and symptoms (eg, exercise intolerance, fatigue, dyspnea, dizziness, presyncope, or syncope) that occur less frequently than daily.(12) **(EG 2)**

For palpitations, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** An observational study of 174 patients with symptoms suggestive of cardiac arrhythmia (45% of whom had palpitations) who were discharged from the emergency department with a patch-type cardiac monitor found, at a median device wear time of 6.9 days, that 48% of patients had significant arrhythmias, and 10% were symptomatic at the time of the arrhythmia. Median time to first arrhythmia was 1 day; however, the median times to first episode of ventricular tachycardia, 3-second or greater pause, and second-degree or third-degree heart block were 3.1, 4.2, and 5.8 days, respectively, which are all beyond the monitoring capability of a Holter monitor. Although 53% of patients did not have an arrhythmia during a triggered event, the authors stated that a negative finding allows for the exclusion of arrhythmia as a possible etiology of patient symptoms. Additional studies that include randomized comparison to Holter monitoring were recommended.(14) **(EG 2)** An observational study of 26,751 patients (40% of whom had palpitations) evaluated the efficacy of a patch-type cardiac monitor and found, at a mean wear time of 7.6 days, that 60% of patients had any kind of arrhythmia and 17.3% of patients had atrial fibrillation. Of the patients with symptomatic arrhythmias, 47% of arrhythmias were detected in the first 2 days of monitoring and 92% were found by the eighth day of monitoring.(17) **(EG 2)** An observational study of 146 patients with suspected cardiac arrhythmia found that a 14-day patch-type cardiac monitor (median wear time of 11.1 days) detected 96 arrhythmia events, which was significantly more than the 61 arrhythmia events that were detected by simultaneous use of a 24-hour Holter monitor (median wear time of 1 day).(1) **(EG 2)** A cross-sectional study of 3209 pediatric patients with suspected arrhythmia, 35.5% of whom had palpitations, found that a 14-day patch-type cardiac monitor detected arrhythmias in 10% of patients with palpitations. The authors noted that 44% of all first-detected arrhythmias and 50.4% of first symptom-triggered arrhythmias occurred after 48 hours of monitoring.(18) **(EG 2)** A specialty society guideline notes that patch-type cardiac monitors, when worn for greater than 7 days, have an estimated diagnostic yield of 70% to 85% in the evaluation of palpitations.(3) **(EG 2)**

For paroxysmal atrial fibrillation, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** An observational study of 74 patients with paroxysmal atrial fibrillation who underwent simultaneous 24-hour Holter monitoring and patch-type cardiac monitoring found that both devices detected all 25 episodes of atrial fibrillation at 24 hours. In the second phase of the study, patients were encouraged to wear the patch-type monitor for up to 2 weeks; 49 patients completed the study, and the remainder discontinued the study for a variety of reasons. Of the entire cohort of 74 patients, additional episodes of atrial fibrillation were detected in 58% of patients. Longer monitoring time was associated with detection of an increased number of episodes of atrial fibrillation. As a result of the use of the patch-type cardiac monitor, 28% of patients had a change in management, such as a change in antiarrhythmic medication, anticoagulation treatment, or recommendation for pacemaker placement.(25) **(EG 2)** An observational study of 26,751 patients (24% of whom had suspected paroxysmal atrial fibrillation) evaluated the efficacy of a patch-type cardiac monitor and found, at a mean wear time of 7.6 days, that 60% of patients had any kind of arrhythmia and 17.3% of patients had atrial fibrillation. Of the patients with symptomatic arrhythmias, 47% of arrhythmias were detected in the first 2 days of monitoring and 92% were found by the eighth day of monitoring.(17) **(EG 2)** A retrospective analysis of 1171 monitoring reports from patients with stroke or transient ischemic attack who underwent ambulatory cardiac rhythm monitoring with a patch-based system found that the median analyzable time relative to the total wear time was 98.7%, and atrial fibrillation was present in 5% of all reports. The mean duration of time to the first episode of paroxysmal atrial fibrillation was 1.5 days, with 14.3% of first paroxysmal atrial fibrillation episodes occurring after 48 hours.(26) **(EG 2)**

For presyncope, syncope, or other transient loss of consciousness, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** An observational study of 125 patients (37 of whom had presyncope) evaluated the efficacy of a patch-type cardiac monitor and found, at a wear time of at least 7 days, that 38% of patients had a clinically significant arrhythmia, 42% had a clinically insignificant arrhythmia, and 18% had normal sinus rhythm. Patient adherence was 98%, and 24% of patients had a change in management as a result of monitoring, including implantation of a pacemaker or cardioverter-defibrillator, ablation therapy, or a change in medication.(27) **(EG 2)** An observational study of 26,751 patients (15% of whom had syncope or presyncope) evaluated the efficacy of a patch-type cardiac monitor and found, at a mean wear time of 7.6 days, that 60% of patients had any kind of arrhythmia and 17.3% of patients had atrial fibrillation. Of the patients with symptomatic arrhythmias, 47% of arrhythmias were detected in the first 2 days of monitoring and 92% were found by the eighth day of monitoring.(17) **(EG 2)** A cross-sectional study of 3209 pediatric patients with suspected arrhythmia, 14% of whom had syncope, found that a 14-day patch-type cardiac monitor detected arrhythmias in 6.7% of patients with syncope. The authors noted that 44% of all first-detected arrhythmias and 50.4% of first symptom-triggered arrhythmias occurred after 48 hours of monitoring.(18) **(EG 2)** A specialty society guideline states that continuous or intermittent ambulatory electrocardiographic monitoring, such as that performed by a patch-type cardiac monitor, is useful to evaluate whether symptoms such as palpitations, presyncope, or syncope are caused by a ventricular arrhythmia.(4) **(EG 2)** A specialty society guideline states that the patch-type cardiac monitor can be considered an alternative to the external (non-implantable) loop recorder for evaluation of syncope that is suspected to be of arrhythmic etiology; because it does not have leads and is self-applied, it may improve patient adherence.(28) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(33); 42 CFR 422.101(34)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(35); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(36); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(37)

Medicare Coverage Determinations: Medicare Coverage Database(38)

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Codes

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