Clinical Policy Title: Real-time outpatient cardiac monitoring

Clinical Policy Number: 04.01.01

Effective Date: September 1, 2013
Initial Review Date: March 21, 2013
Most Recent Review Date: March 6, 2018
Next Review Date: March 2019

Policy contains:
- Remote non-invasive cardiac event monitoring.
- Cardiac outpatient telemetry.
- Attended surveillance.

Related policies:

CP# 04.01.05 Implantable cardiac loop recorder

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of real-time outpatient cardiac monitoring to be clinically proven and, therefore, medically necessary when all of the following criteria are met (Al-Khatib, 2017; Shen, 2017; Korompoki, 2017; Dahal, 2016; Kirchhof, 2016; Khairy, 2014; Agency for Healthcare Research and Quality [AHRQ], 2007):

- Other cardiac-related testing and/or monitoring, recording, and telemetry have been unrevealing. The ordering physician/health care provider must document prior testing performed and the results.
- For the detection, characterization, and documentation of any of the following:
  - Symptomatic transient or paroxysmal dysrhythmia when the frequency of the symptoms is limited and the use of a 24-hour ambulatory electrocardiogram (ECG) is documented in the medical record to be unlikely to capture and record a non-life-threatening dysrhythmia.
  - Other paroxysmal supra-ventricular arrhythmias.
  - Evaluation of various brady arrhythmias.
- Intermittent bundle branch block.
- Individuals recovering from cardiac surgery who have had documented atrial arrhythmias.
- Individuals with symptomatic underlying structural disease.
- Individuals with no structural heart disease but who have recurrent severe symptoms (i.e., recurrent syncope), in whom all testing is negative and an implantable event recorder is contemplated.
- Individuals with uncontrolled atrial fibrillation post-pneumonectomy.

- Prolonged monitoring is required specifically to ensure the absence of asymptomatic arrhythmias, or QT interval or ST changes including, but not limited to, any of the following conditions:
  - Recurrence of atrial fibrillation prior to the discontinuation of anticoagulation therapy.
  - Drug response for those receiving antiarrhythmic therapy.
  - Pro-arrhythmia associated with anti-arrhythmic and other medication.
  - Silent ischemia for those requiring anti-ischemic therapy.

**Limitations:**

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at [http://ahca.myflorida.com/Medicaid/](http://ahca.myflorida.com/Medicaid/).

All other uses of real-time outpatient cardiac monitoring are not medically necessary. Examples include, but are not limited to, the following:

- When real-time outpatient cardiac monitoring is unlikely to provide clinical data or information beyond that which has already been obtained from a previous test, or if other testing could be expected to provide the data and/or information needed for the diagnosis or treatment of the patient's symptoms and condition (e.g., 24-hour Holter monitor).
- For individuals considered to be at high risk for clinically significant recurrent dysrhythmias (e.g., ventricular tachycardia or ventricular fibrillation).
- Screening.
- With a Holter monitor, or other event recorder, performed on the same individual on the same day.
- As outpatient monitoring in an individual recently discharged from a facility immediately following a myocardial infarction.
- In anyone with potentially life-threatening arrhythmias that require inpatient monitoring.

Qualified personnel must provide surveillance in receiving centers and direction in emergent situations.
Outpatient cardiac monitoring that extends beyond 30 consecutive days is limited to a maximum of two 30-consecutive day periods within a 12-month time frame.

Alternative covered services:

- Holter monitor.
- External cardiac loop recorders.
- Implantable real-time cardiac monitors.
- In-hospital cardiac telemetry.
- Oral pharmacotherapy.

Background

Cardiac arrhythmias may result in abnormally high or low heart rates and are marked by symptoms such as palpitations, dizziness, or fainting episodes. They may go undetected, occur at any time, and be unpredictable in nature, making a correct diagnosis a difficult task. Effective clinical treatment and management are dependent upon an accurate diagnosis.

Cardiac monitoring devices have been developed to assist in the diagnosis of arrhythmias. Cardiac event recorders that require individual patient input are only as good as the individual’s ability to recognize an arrhythmia and activate the unit. Outpatient Holter monitors are short-term and limited by their ability to record ECG information for up to 48 hours. The short duration and capacity of a Holter monitor limits its diagnostic yield; as such, it is most appropriate for recording episodes that occur at least on a daily basis.

Real-time outpatient cardiac monitoring:

Real-time outpatient cardiac monitoring has been developed for patients for whom a longer period of time is needed to identify arrhythmias for a definite diagnosis. These devices provide continuous outpatient ECG monitoring for weeks, up to a one month (30 days) period, and are used to monitor heart rhythm outside a facility setting for people with non-life threatening cardiac arrhythmias.

A real-time outpatient cardiac monitoring uses an automatically activated system to either capture or transmit dysrhythmic episode information. These monitors have an extended memory and an automatic real-time event notification ability that use either computer dialing of conventional landlines or cellular communication technology. The notification ability relies on a computer program that continually analyzes heart rhythm data as they are received. The monitor automatically transmits ECG-recorded data to a central station where the program detects an arrhythmia. The individual wearing the monitor may also transmit symptoms to the central station for further analysis.
The automatic activation enables a rapid telephonic submission to a perpetually manned (attended) receiving station (surveillance) and an immediate interpretation of irregular heart rhythm activity by ECG. The American Medical Association (AMA) defines attended surveillance as the immediate availability of a remote technician to respond to rhythm or device alert transmissions from a patient, either from an implanted or wearable monitoring or therapy device, as they are generated and transmitted to the remote surveillance center (AMA, 2014).

Several U.S. Food and Drug Administration (FDA)-approved devices classified as an arrhythmia detector and alarm (including ST-segment measurement and alarm, product code DSI) are available for marketing in the United States (FDA, 2017a, b, c, d, and e). Emerging technology includes new devices in this category that are wireless, implantable ECG monitors with real-time monitoring capability.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- AHRQ’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches in January 22, 2018. Search terms were: “Cardiac monitoring,” “Arrhythmias, Cardiac/analysis” (MeSH), “Arrhythmias, Cardiac/diagnosis” (MeSH), “Atrial Fibrillation/classification” (MeSH), “Atrial Fibrillation/diagnosis” (MeSH), and “Electrocardiography, Ambulatory” (MeSH).

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Studies of the clinical utility of outpatient cardiac monitoring have been of various sizes and duration. Kadish (2010) studied 26,438 patients who had undergone outpatient cardiac telemetry during a nine-month period, tracking how many events transmitted by these monitors measured emergent arrhythmias. Of these patients, 5,459 (21 percent) had an arrhythmic event that required physician notification, and 262 (1 percent) patients had an event that would be considered potentially emergent. The potentially emergent events included 42 with sustained bradycardia at less than 30 heart beats per
minute, 100 patients with sinus pauses of six seconds or longer, and 120 patients with wide-complex
tachycardia. Lack of an appropriate comparison group limited the results of this and other studies, and
does not allow for conclusions regarding benefit of outpatient cardiac telemetry over and beyond that
offered by current medical standards.

One randomized controlled trial (RCT) compared the diagnostic yield of an outpatient telemetry system
(CardioNet Mobile Cardiac Outpatient Telemetry™ [MCOT], Malvern, Pennsylvania) to patient-activated
external looping event monitors in patients with symptoms suggestive of a significant cardiac
arrhythmia(s) (Rothman, 2007). The study engaged 18 centers with patients randomized to either MCOT
or standard loop event monitoring for up to 30 days. The study subjects presented with symptoms of
severe palpitations (81 percent) with a non-diagnostic 24-hour Holter monitor, pre-syncope (33
percent), or syncope (16 percent). The primary endpoint was the exclusion or confirmation of a
probable arrhythmic cause of the participant’s symptoms. Secondary endpoints included the detection
of non-symptomatic and symptomatic clinically significant arrhythmias and the length of time to
diagnosis. A total of 266 participants completed the monitoring period.

Diagnosis was made in 88 percent of the MCOT participants compared to 75 percent of those with
standard loop recorders. In a subgroup of participants presenting with pre-syncope or syncope, a
diagnosis was made in 89 percent of the MCOT subjects compared to 69 percent of those with standard
loop recorders. MCOT was superior to standardized loop monitoring in detecting symptoms suggestive
of significant cardiac arrhythmias (38 percent versus 14 percent, respectively). These results suggest that
real-time outpatient cardiac monitoring is superior to a patient-activated external loop recorder for
detecting and diagnosing cardiac arrhythmias (Rothman, 2007).

NICE recommends the following in patients with suspected paroxysmal atrial fibrillation that is
undetected by standard ECG recording (NICE, 2006):

- A 24-hour ambulatory ECG monitor should be used for those individual with suspected
asymptomatic episodes or symptomatic episodes less than 24 hours apart.
- An event recorder ECG should be used in those individuals with symptomatic episodes more
than 24 hours apart.

The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of
Cardiology (ESC) ventricular arrhythmia guidelines make a distinction between the indications for
continuous 24- to 48-hour Holter monitoring and intermittent monitoring with event (Zipes, 2006;
updated by Al-Khatib, 2017). Based on class one, level A evidence, ambulatory ECG is appropriate when
there is a need to clarify the diagnosis by detecting arrhythmias, QT-interval changes, T-wave alternans,
or ST changes to evaluate risk, or to judge therapy. Event monitors are indicated when symptoms are
sporadic and related to arrhythmias such as syncope, when a symptom-rhythm correlation cannot be
established by conventional diagnostic methods. A 24- to 48-hour Holter monitor is appropriate
whenever the arrhythmia is known or suspected to occur at least once a day. For sporadic episodes
producing dizziness, syncope or palpitations, conventional event monitors are more appropriate
because they are able to record over longer periods of time. Continuously recording monitors that have
both patient-activated and automatic triggers appears to improve the diagnostic yield of event monitors.

A clinical competence statement on remote cardiac monitoring suggests that the frequency of symptoms may guide physician decisions about which type of monitoring to use for a particular individual (AHRQ, 2007). For individuals with infrequent symptoms, intermittent event recorders may be more cost-effective. Continuous recording devices are recommended for individuals with daily symptoms that may be related to recurrent, unexplained palpations, heart rhythm disturbances, syncope, or near syncope episodes. Continuous monitoring is also indicated for individuals receiving antiarrhythmic therapy in order to assess drug response, monitor the rate of atrial fibrillation, exclude pro-arrhythmia, assess silent ischemia, and monitor anti-ischemia therapy (AHRQ, 2007).

In the diagnosis of patients with symptoms of a cardiac arrhythmia, real-time outpatient cardiac monitoring provides a significantly higher yield than standard cardiac loop recorders. This result was more pronounced in patients presenting with symptoms of syncope or presyncope. Outpatient cardiac monitoring was superior to loop recorders for detecting clinically significant arrhythmias, with a shorter time to diagnosis.

**Policy updates:**

The Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS) Expert Consensus Statement on the Recognition and Management of Arrhythmias in Adult Congenital Heart Disease concurs with guidelines identified in the original policy findings (Khairy, 2014). Indications for ambulatory monitoring and selection of recording technique in symptomatic patients with congenital heart disease are similar to those for the general population. Standard Holter monitoring is best suited for the evaluation of daily symptoms or arrhythmias. Noninvasive devices capable of longer-duration continuous recordings (typically two to four weeks) are best suited for evaluating sporadic symptoms such as syncope. Although data are limited, in select cases where the index of suspicion for a malignant arrhythmia is high but noninvasive monitoring in not feasible or has been unrevealing, an implantable loop recorder may prove valuable (Khairy, 2014).

Two systematic reviews and meta-analyses concluded that prolonged invasive and non-invasive cardiac monitoring improves detection of atrial fibrillation in survivors of cryptogenic stroke or transient ischemic attack, although significant heterogeneity exists across individual studies (Korompoki, 2017; Dahal, 2016). These results and findings from the Atrial Fibrillation Network/European Heart Rhythm Association (AFN/EHRA) consensus conference (Kirchhof, 2016) suggest that improved detection of persistent and paroxysmal atrial fibrillation using prolonged monitoring (usually > seven days), which would remain otherwise undetected, may lead to improved use of anticoagulants and stroke prevention, although prospective studies are needed to confirm these assumptions. Prolonged monitoring appears to benefit high risk populations, in particular, such as those over age 65, survivors of ischemic stroke, and persons who have undergone more extensive prior testing for arrhythmias. These results are consistent with previous findings. Therefore, no changes to the policy are warranted.
In 2018, we added one new health technology assessment comparing the impact of long-term continuous ECG monitors to external loop recorders in detecting symptoms of cardiac arrhythmia (Health Quality Ontario, 2017) and two updated guidelines (Al-Khatib, 2017; Shen, 2017). Although both types of monitors were more effective than a 24-hour Holter monitor, there was no difference in their ability to detect intermittent cardiac arrhythmia (Health Quality Ontario, 2017). The guideline updates are consistent with the current policy. No policy changes are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Health Quality Ontario (2017) Long-term continuous ambulatory ECG monitors and external cardiac loop recorders for cardiac arrhythmia | Key points:  
- Health technology assessment of the impact of long-term continuous ECG monitors versus external loop recorders in detecting symptoms of intermittent cardiac arrhythmia. No included studies directly compared the two devices. Seven studies assessed long-term continuous monitors and five assessed external loop recorders, both compared to 24-holter monitoring.  
- Overall quality: low based on Grading of Recommendations Assessment, Development, and Evaluation criteria  
- An indirect comparison found both types of devices were more effective than a 24-hour Holter monitor but not substantially different in their ability to detect symptoms (risk difference 0.01; 95% confidence interval -0.18 to 0.20).  
- In instances where more detailed information on arrhythmias is needed (e.g., examining days or weeks of data to determine the most effective treatment regimen), a long-term continuous monitor might be preferable to an external loop recorder. |
| Korompoki (2017) Atrial fibrillation detection rates using different methods of ECG monitoring in transient ischemic attack (transient ischemic attack) | Key points:  
- Systematic review and meta-analysis of 17 prospective observational studies and RCTs (1,163 total patients) comparing ECG monitoring (> 12 hours) techniques.  
- Pooled atrial fibrillation detection rate (≥ 30 seconds) for all methods = 4% (95% confidence interval [CI] 2 to 7%), and rose with duration: 4% (24 h), 5% (24 h to 7 days) and 6% (>7 days).  
- Diagnostic yield was higher in:  
  - Selected (higher age, more extensive testing for arrhythmias before enrolment, or presumed cardioembolic/cryptogenic cause) vs. unselected cohorts (7% vs. 3%, respectively).  
  - Invasive vs. non-invasive monitoring (11% vs. 4%).  
- Significant heterogeneity among studies was noted; prospective studies are needed. |
| Kirchhof (2016) for the AFN/EHRA Consensus recommendations | Key points:  
- Screening for unknown atrial fibrillation and initiation of anticoagulation has the potential to prevent strokes in persons with undiagnosed atrial fibrillation.  
- Prolonged non-invasive or invasive ECG screening for atrial fibrillation, which remains undetected by current ECG monitoring practices, may improve detection.  
- We recommend the establishment of more widespread screening programs for persistent and paroxysmal atrial fibrillation in those over age 65, and in populations at risk, particularly survivors of ischemic stroke. |
Prolonged cardiac monitoring to detect atrial fibrillation after cryptogenic stroke or transient ischemic attack

Key points:
- Meta-analysis of four RCTs (1,149 total patients).
- Compared to short-term cardiac monitoring (≤ 48 hours duration), prolonged cardiac monitoring (> 7 days) significantly increased atrial fibrillation detection (≥ 30 seconds duration), but no significant differences noted in recurrent stroke or transient ischemic attack, or mortality.
- Patients who underwent prolonged monitoring were more likely to be on anticoagulation at follow-up.

References

Professional society guidelines/other:


Khairy P, Van Hare GF, Balaji S, et al. PACES/HRS expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Canadian Heart Rhythm Society (CHRS), and the International Society for Adult Congenital Heart Disease (ISACHD). Can Jour Cardiol. 2014; 30(10): e1 – e63. DOI: 10.1016/j.cjca.2014.09.002.


Peer-reviewed references:


CMS National coverage determination (NCDs):


Local coverage determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
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<td>93228</td>
<td>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</td>
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<tr>
<td>93229</td>
<td>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</td>
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