CLINICAL MEDICAL POLICY	
Policy Name:	Single-use Ambulatory Electrocardiographic Monitors (e.g., Zio Patch)
Policy Number:	MP-076-MD-DE
Responsible Department(s):	Medical Management
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 8

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary single-use ambulatory electrocardiographic monitors.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Zio Patch – Is a single-use external ambulatory ECG device that continuously records ECG data for up to 17 days. It is intended to capture, analyze and report symptomatic and/or continuous electrocardiogram information for long-term monitoring in adult patients 18 years of age or older who may be asymptomatic or suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue or anxiety.

PROCEDURES

1. Highmark Health Options considers the use of the Zio Patch medically necessary when:
   A. The patient must be 18 years of age or older on the date of service; AND
   B. The patient experiences infrequent symptoms (e.g., occurrence of symptoms are less than every 48 hours) and is unlikely to be diagnosed with use of a Holter monitor: AND
   C. Results of the monitoring will be used to guide medical management; AND

   In addition one of the following conditions must be present for use of the device:
   A. Unexplained syncope, pre-syncope and/or palpitations; OR
   B. In patients with atrial fibrillation in order to monitor for asymptomatic episodes in order to evaluate treatment response; OR
   C. In the assessment of asymptomatic or symptomatic arrhythmia in patients who are status-post electrophysiology ablation procedures (e.g., patients with atrial fibrillation that have been ablated and in whom discontinuation of systemic anticoagulation therapy is under consideration); OR
   D. In patients with cryptogenic stroke who have had a negative standard work-up for atrial fibrillation including a 24 hour Holter monitor.
   E. Testing is limited to no more than twice in a one year period.

   Alternate devices include:
   A. 12-lead EKG
   B. 24-48 hour or 7 day continuous ambulatory monitoring, including Holter monitors
   C. Long-term continuous monitoring for up to 30 days
   D. External loop recorders
   E. Insertable loop recorders, which can record event for up to 3 years for arrhythmias that can occur months apart

2. Contraindications
   According to the manufactures information there are no known contraindications for the Zio patch. The manufacturer does warn that the device should not be used in the following situations:
   A. Patients with known allergic reactions to adhesives or hydrogels or with a family history of adhesive skin reactions;
   B. In combination with external cardiac defibrillators or high-frequency surgical equipment;
   C. Near strong magnetic field or devices, such as magnetic resonance imaging (MRI)
   D. Patients with a neurostimulator as the neurostimulation may disrupt the quality of the ECG data;
   E. Patients without the competency to wear the device for the prescribed duration;
   F. The device has not been tested in patients receiving any form of pacing therapy or patients < 18 years of age or subgroups in whom cardiac rhythms may not be detected accurately or may be classified inappropriately.

3. When the Zio patch ambulatory cardiac monitoring services are not covered
   Services are not covered and considered not medically necessary when the above medical necessity guidelines are not met.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the Zio Patch is outpatient.

GOVERNING BODIES APPROVAL

The ZP model Z100 was FDA approved on May 9, 2009 as a prescription only device for single-use ECG monitoring. The device can be worn up to 14 days in individuals that experience intermittent symptoms such as syncope, palpitations, or shortness of breath and chest pain.

In July 2012, the FDA approval was extended to include patients who are asymptomatic or suffer from intermittent symptoms.

The Zio ECG Utilization Service (ZEUS) system received FDA approval in July 2009 for processing single-lead ECG data stored for up to 14 days. The device is intended to be used only by qualified medical professionals; and downloads, stores, analyzes and sorts ECG data to generate a report, which is sent to the patient's physician to review and determine a diagnosis.

In June 2015, the Zio SR (Skyrunner) ECG service was cleared for capturing, analyzing, and reporting symptomatic and/or continuous ECG information for up to 14 days monitoring. The device is indicated for use in adults aged ≥ 18 who can be symptomatic or suffer from transient symptoms. The reported ECG metrics include single lead analysis on a beat-by-beat basis, heart rate measurement, and rhythm analysis. The analysis does not contain diagnostic interpretation however it is provided for review by the provider to render a diagnosis based on clinical judgment and experience.

CODING REQUIREMENTS

Procedure Codes

CPT Codes	Description
0295T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
0296T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report
0298T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation

Diagnosis Codes

ICD-10 Codes	Description
A88.1	Epidemic vertigo
I44.0	Atrioventricular block, first degree
I44.1	Atrioventricular block, second degree
I44.2	Atrioventricular block, complete
I44.30	Unspecified fascicular block
I44.39	Other atrioventricular block
I44.4	Left anterior fascicular block
I44.5	Left posterior fascicular block
I44.60	Unspecified fascicular block
I44.69	Other fascicular block
I44.7	Left bundle-branch block
I45.0	Right fascicular block
I45.10	Unspecified right bundle-branch block
I45.19	Other right bundle-branch block
I45.2	Bifascicular block
I45.3	Trifascicular block
I45.4	Nonspecific intraventricular block
I45.5	Other specified heart block
I45.6	Pre-excitation syndrome
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders
I45.9	Conduction disorders, unspecified
I47.0	Re-entry ventricular arrhythmia
I47.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I48.0	Paroxysmal atrial fibrillation
I48.1	Persistent atrial fibrillation
I48.2	Chronic atrial fibrillation
I48.3	Typical atrial flutter
I48.4	Atypical atrial flutter
I48.91	Unspecified atrial fibrillation
I48.92	Unspecified atrial flutter
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I49.1	Atrial premature depolarization
I49.2	Junctional premature depolarization
I49.3	Ventricular premature depolarization
I49.40	Unspecified premature depolarization
I49.49	Other premature depolarization
I49.5	Sick sinus syndrome

I49.8	Other specified cardiac arrhythmias
I49.9	Cardiac arrhythmia, unspecified
R00.0	Tachycardia, unspecified
R00.1	Bradycardia, unspecified
R00.2	Palpitations
R07.1	Chest pain on breathing
R07.2	Precordial chest pain
R07.81	Pleurodynia
R07.82	Intercostal chest pain
R07.89	Other chest pain
R07.9	Chest pain, unspecified
R42	Dizziness and giddiness
R55	Syncope and collapse
R94.31	Abnormal electrocardiogram [ECG] [EKG]

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

The Zio Patch (iRhythm Technologies Inc.) is the first commercially available, single-use, wireless and waterproof ambulatory ECG monitor. The Zio Patch provides non-continuous or continuous monitoring for up to 14 days for patients with suspected cardiac arrhythmia(s). The device is configured with a single lead, monitor, and data storage in an adhesive patch that is approximately 2 x 5 inches. ECG data are stored in an internal flash drive and a patch is applied to the patient's left pectoral area, and the patient is instructed to wear the patch until it no longer adheres to their skin, or up to 14 days. Patients can also press a button on the Zio Patch device when they recognize a symptomatic episode. The patient mails the monitor to a central diagnostic testing facility for evaluation. The Zio ECG Utilization Service (ZEUS) system is a comprehensive system that processes and analyzes received ECG data captured by long-duration, single-lead, continuous recording diagnostic devices (e.g., the Zio Patch and Zio Event Card). The Zio Patch/Zio Event Card is a new technology that competes with Holter monitoring, event monitoring, and mobile cardiac outpatient telemetry (MCOT).

Barrett et al (2014) reported on a small study of 146 patients that underwent simultaneous ambulatory ECG recording with 24 hour Holter and a 14-day adhesive patch monitor. The results state that over the total time of both devices, the adhesive patch monitor detected 96 arrhythmia events compared with 61 identified with the Holter. The study showed that patients were comfortable using the patch and experienced significantly fewer impacts on activities of daily living. The authors concluded that the use of the prolonged duration of monitoring with the single use adhesive device could replace conventional Holter monitoring. Note: this study was partial funded by iRhythm Technologies, the developer of the Zio patch.

Cheung et al (2014) reviewed the results of the study above and reported observations and concerns regarding the Zio patch. The authors reported that while the Holter monitor detected more events during the initial 24-hour period, the adhesive patch monitor detected more arrhythmia events over total wear

time. However, it was noted that there is loss of quality, automated rhythm analysis and inability to detect myocardial ischemia needs to be addressed prior to the implementation of these new devices.

Hayes Inc.
In 2017 Hayes published an annual review on the Zio patch (ZP) long-term ambulatory cardiac rhythm monitoring. The report stated that there are no newly published studies on this technology and no changes to the existing report from 2015 are needed. The insights from the review indicate that:

- high-quality studies are need to better evaluate ZP clinical performance and clinical utility in regards to impacts on treatment decisions and patient outcomes;
- ZP devices are easy to use and can remain in place during all activities of daily living, including sleep, exercise and bathing. Patient preference for and compliance with monitoring may be greater for these devices than more standard cumbersome devices;
- ZP devices may facilitate follow-up in patients presenting to the ER with symptoms suggestive of arrhythmia. The process of applying the device upon discharge and instructing the patient to follow-up with a personal physician is straightforward and may be more prompt than arranging for the use of a Holter.

Hayes assigned two ratings for ZP.
The '**C**' rating was given for the use of the ZP for longer-term ambulatory cardiac rhythm ECG monitoring in adults. This rating reflects the low-quality body of evidence suggesting continued detection of clinically significant arrhythmias, beyond, 24 hours, using the device compared to 24 hour Holter monitoring alone and there is minimal device-related safety issues. Substantial uncertainty remains due to the low number of studies using a reference test and the paucity of data on clinical utility in this patient population.

The '**D2**' rating was given for the use of ZP on longer-term ambulatory cardiac rhythm ECG monitoring in children (≤ 18 years of age). This rating reflects the paucity of evidence on diagnostic accuracy and clinical utility in this patient population.

Up-to-Date
A review of ambulatory ECG monitoring was performed May 2018. The medical necessity of this type of monitoring was supported and a brief overview of several types of devices was provided. The ZIO patch was included in the review. The review did not indicate that the use of the device is not medically necessary but rather it was grouped with all types of ambulatory ECG monitors and covered indications were listed.

NICE
There is limited evidence on the effectiveness of the Zio Service compared with standard care. The 2 available comparative studies do not compare Zio Service with a monitoring device that uses a similar monitoring period, instead comparing 14-day Zio Service monitoring with 24-hour Holter monitoring. The sizes of the 2 comparative studies on Zio Service are relatively small with a total of 220 people included. Although these studies were carried out in the US, they are likely to be relevant to the current NHS care pathway because they compared Zio Service with 24-hour Holter monitoring, which is considered standard care in the NHS. The 2 very large retrospective studies are less informative because they were non-comparative and retrospective.

More studies comparing the Zio Service with ambulatory electrocardiogram (ECG) including Holter and event monitoring over 7 days or longer would be useful to determine its clinical and cost effectiveness in the NHS. Two studies, which will compare the Zio Service with standard monitoring in a UK cohort, are currently in progress.

ECRI Institute provided a review on the iRhythm Zio Patch in 2014. There were a total of three abstracts from published journal articles and nine abstracts from conferences that compared the Zio Path as a continuous recording ECG monitor. The report suggested that the Zio Patch can work better than a Holter monitor by increased diagnostic yield in specific circumstances.

In 2012, Turakhia et al reported on the clinical experience and diagnostic yield from a national registry on the 14 day ECG patch monitoring. The study evaluated 18,236 consecutive patients in the United States wearing the 14 day patch from October 2010 to October 2011. The mean age was 60 years and 54% of the patients were female. Average wear time was reported as 7.1 days. The authors concluded that there was a high variation in the time to the first and first symptomatic arrhythmia, noting that 41.9% of patients had their first symptomatic arrhythmia beyond 48 hours. However, extended (14) day monitoring can increase diagnostic yield, regardless of arrhythmia type.

POLICY SOURCE(S)

Hayes Inc. Health Technology Brief. Zio Patch (iRhythm Technologies Inc.) Long-Term ambulatory Cardiac Rhythm Monitoring. Original publication November 5, 2015 and annual review October 20, 2017. Accessed October 4, 2018.

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Turakhia M, Hoang D, Zimetbaum P, Yang F, Froelicher V, Heidenrich P. Clinical experience and diagnostic yield from a national registry of 14-day ambulatory ECG patch monitoring. Volume 59, Issue 12Supplemnt, March 2012. Accessed October 9, 2018.

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Policy History

Date	Activity
10/05/2018	Initial policy developed
12/11/2018	QI/UM Committee approval
02/18/2019	Provider effective date