

**Subject: Cardiac Event Monitors**

**Background:** Cardiac arrhythmias are abnormal heart rhythms that can cause palpitations, weakness, dizziness, fainting, blood clots, or death. There are a wide variety of treatments available for arrhythmias, however, obtaining an accurate diagnosis can be difficult since arrhythmias can occur infrequently and unpredictably and may not cause obvious symptoms. Remote cardiac monitoring technologies allow home electrocardiographic (EKG) monitoring of individuals with suspected cardiac arrhythmias or at risk for developing arrhythmias. A variety of ambulatory external EKG monitoring systems have been developed. These include 24–48-hour Holter monitoring, 7–14-day patch-type monitoring, self-activated event monitors, and auto-triggered loop monitors. To detect infrequent arrhythmias, members can undergo 24 to 48 hours of continuous outpatient EKG recording with a Holter monitor. A limitation of this device is that repeated monitoring sessions may be necessary if an arrhythmia does not occur during the first 1 or 2 days. Another method for detection of infrequent arrhythmias is the use of an event recorder, which stores 1 to 2 minutes of EKG data as soon as the individual experiences symptoms and presses a button to activate the device. Although this technique enables a much longer period of monitoring, some arrhythmias do not cause obvious symptoms and some symptomatic members fail to turn on the recorder at the right time.

The following are descriptions of various cardiac event monitors:

- Cardiac event detection monitoring (implantable loop monitoring): An implantable loop recorder (ILR) is rarely the preferred initial test for ambulatory ECG monitoring (AECG). However, this test can be useful for members with infrequent (e.g. less than monthly) symptoms that are potentially harmful to the individual. An ILR is implanted subcutaneously in a member's upper left chest and left for several months.
- Continuous AECG monitoring (24- or 48-hour Holter monitoring): The Holter monitor reports total heart beats as well as average and maximum/minimum heart rates. It provides representative hourly samples of the ECG tracing and episodes of tachyarrhythmia and the etiology of the arrhythmias as well as pauses. The monitor detects a number of premature beats (supraventricular and ventricular), ST segment changes, member-reported symptoms associated ECG findings and the longest R-R interval with pauses greater than three seconds. The Holter monitor may be the preferred ambulatory ECG monitoring test for members with daily or near daily symptoms and for those who would prefer a comprehensive assessment of all cardiac activity over the given 24-48 hour interval.
- Continuous AECG monitoring for periods greater than every 48 hours (e.g. Zio® Patch): The Zio® Patch is a single-use AECG monitor that has the capability of collecting data for up to 14 days for those with suspected cardiac arrhythmias (e.g. ventricular tachycardia (VT), supraventricular tachycardia (SVT), paroxysmal atrial fibrillation (AF), atrioventricular block, symptomatic bradycardia and greater than 3-second pauses.
- External cardiac event detection monitoring (e.g. external loop monitoring): An external loop monitor has the capability to monitor an individual for long durations (e.g. up to seven days) and thus has a higher chance of providing a diagnosis to those whose symptoms occur infrequently. It is recommended for those with infrequent short-duration transient symptoms, reoccurring over weeks or months.

- Mobile cardiac outpatient telemetry monitoring (e.g. CardioNet®, Inc.): MCOT monitors members in real-time using built-in detection algorithms and cellular technology. It holds up to 96 hours of memory and allows providers to capture significant arrhythmic events, even when no symptoms are experienced.

### **Policy and Coverage Criteria:**

Harvard Pilgrim Health Care (HPHC) considers the following cardiac event monitors medically necessary when age specific and device specific criteria are met:

#### **General Criteria:**

- Continuous ambulatory electrocardiography (AECG) monitoring (24- or 48-hour Holter monitoring) is considered medically necessary when:
  - Documentation confirms infrequent arrhythmia is unlikely to be diagnosed by a standard 12-lead ECG AND results of this testing will provide diagnostic or treatment information necessary for the management of the member beyond what would be provided by the 12-lead ECG
- External cardiac event detection monitoring (e.g. external loop monitoring) is considered medically necessary when:
  - Documentation confirms infrequent arrhythmia is unlikely to be diagnosed by a 24- or 48-hour Holter monitor AND results of this testing will provide diagnostic or treatment information necessary for the management of the member beyond what would be provided by the continuous 24- or 48-hour Holter monitor
- Cardiac event detection monitoring (e.g. implantable loop monitoring), is considered medically necessary when:
  - Documentation confirms infrequent arrhythmia is unlikely to be diagnosed by a 24- or 48-hour Holter monitor and/or external loop monitor AND results of this testing will provide diagnostic or treatment information necessary for the management of the member beyond what would be provided by the continuous 24- or 48-hour Holter monitor and/or external loop monitor
- Mobile cardiac outpatient telemetry monitoring (MCOT) is considered medically necessary when:
  - Documentation confirms trial of other appropriate testing/monitoring (i.e. 24- or 48-hour Holter monitor and/or external loop monitor) that did not provide necessary diagnostic information; AND
  - Individual with a non-diagnostic Holter monitor or 48-hour telemetry experiences arrhythmia or infrequent symptoms unlikely to be diagnosed by Holter monitoring
- Continuous ambulatory electrocardiography (AECG) monitoring for periods greater than 48-hours (e.g. Zio® Patch) considered medically necessary when:
  - Documentation confirms trial of other appropriate testing/monitoring (i.e. 24- or 48-hour Holter monitor and/or 48-hour telemetry) that did not provide necessary diagnostic information; AND
  - Individual with a non-diagnostic Holter monitor or 48-hour telemetry experiences syncope, lightheadedness or infrequent symptoms unlikely to be diagnosed by Holter monitoring

#### **Age-Specific Criteria:**

The provider must also have all prior testing and result documentation and one or more of the following age-specific criteria must be met for monitoring devices to be considered medically necessary:

**Adults:**

- Evaluation of infrequent recurrent symptoms (e.g. presyncope, syncope lightheadedness, palpitations, shortness of breath, chest pains or dizziness) that may be associated with arrhythmia, OR
- Evaluation of members with unexplained recurrent palpitation after complete examination, OR
- Assessment of individuals with documented coronary artery disease (CAD) for silent myocardial ischemia, OR
- Monitoring members who have had surgical or catheter ablation of atrial fibrillation when discontinuation of systemic anticoagulation is being considered, OR
- Assessment of individuals who have had a history of cryptogenic stroke along with evidence of prior non-diagnostic tests, OR
- Evaluation of members with idiopathic hypertrophic or dilated cardiomyopathies to detect arrhythmias.

**Pediatric:**

- Antiarrhythmic drug efficacy, during rapid somatic growth, OR
- Asymptomatic congenital atrioventricular block, non-paced, OR
- Documented or potential long QT syndromes (LQTS), OR
- Hypertrophic or dilated cardiac myopathies, OR
- Palpitations in members with previous surgery for congenital heart disease and significant residual hemodynamic abnormalities, OR
- Previously documented arrhythmia or pacemaker dependency, OR
- Syncope, near syncope associated with exertion or dizziness with known heart disease.

Note: Repeat studies within a 1-year time frame are subject to review based on medical necessity.

**Exclusions:** Harvard Pilgrim Health Care (HPHC) considers cardiac event monitors experimental/investigational for all other indications. In addition, HPHC does not cover:

- Ambulatory electrocardiography (AECG) monitoring managed through mobile devices (e.g. Kardia Mobile, BodyGuardian Remote Monitoring System, iHEART, ViSi Mobile Monitoring System)
- BioTel MCT 3 Lead (MCT 3L)
- Biotronik BioMonitor
- CardioMEMS™
- CardioPatch
- EndoSure™ Wireless Implantable System

**Supporting Information:**

External ambulatory event monitors: Ambulatory event monitors (AEM) , such as the Holter monitor, are either worn continuously and activated only when the patient experiences symptoms or is carried by the patient and applied and activated when symptoms are present. The recorded electrocardiogram (EKGs) are then either stored for future analysis or transmitted by telephone to a receiving station where the EKGs can then be analyzed. AEMs can be used for extended periods of time, typically up to a month until the patient experiences symptoms.

Implantable ambulatory event monitors: An implantable loop recorder is inserted just under the patient's skin in the chest area during an outpatient surgical procedure for patients with infrequent cardiac events requiring long term monitoring. When symptoms are felt, the patient places a hand-held activator over the recorder to activate the storage of cardiac rhythms. This device can be used for more than one year. Auto-triggering technology is also available and can be adapted to memory loop devices. For example, event monitors can be programmed to

detect heart rates greater than 165 beats per minute, less than 40 beats per minute, or an asystole of greater than three seconds.

Kabali et al. (2017) assessed the use of ambulatory electrocardiogram (ECG) monitors, external cardiac loop recorders, and 24-hour Holter monitor in detecting symptoms of cardiac arrhythmia. There was no evidence to suggest that these devices differed in effectiveness.

ECRI Institute (2014) reviewed the significance of the iRhythm Zio® Patch. The review consisted of results presented in abstracts of three published journal articles and nine conference abstracts. It was suggested that the Zio® Patch works as a continuous recording ECG monitor. Two studies suggested that in certain circumstances the Zio® Patch may work better than the standard Holter monitor to increase diagnostic yield. The American College of Cardiology and American Heart Association guidelines (1999) includes any of the following indications for ambulatory ECG monitoring (AECG) monitoring in pediatric members as medically necessary:

- Antiarrhythmic drug efficacy, during rapid somatic growth
- Asymptomatic congenital atrioventricular block, non-paced
- Documented or potential long QT syndromes (LQTS)
- Hypertrophic or dilated cardiac myopathies
- Palpitations in members with previous surgery for congenital heart disease and significant residual hemodynamic abnormalities
- Previously documented arrhythmia or pacemaker dependency
- Syncope, near syncope associated with exertion or dizziness with known heart disease

The Zio Patch is an FDA-approved, outpatient, externalized, single-use cardiac monitor. Unlike Holter monitors, this device can be worn during showering and daily activities and remain on the patient for between 48 hours and 14 days. The device does not require patient activation. The Zio™ EKG Utilization Service (ZEUS) system is a comprehensive system that processes and analyzes received EKG data captured by long-duration, single lead, continuous recording diagnostic devices, such as the Zio™ Patch and Zio™ Event Card.

Barrett et al. (2014) compared the 24-hour Holter monitoring system with a 14-day Zio adhesive patch. This study had 146 participants who wore both a Holter monitor and the Zio Patch. The Holter monitor was worn for 24 hours and the Zio Patch for 14 days. Of the 102 physicians surveyed, 90% thought a definitive diagnosis was achieved using data from the Zio Patch, as opposed to 64% using data from the Holter monitor. 93.7% of patients found the Zio Patch comfortable to wear and 81% indicated they would prefer it over the Holter monitor. During the simultaneous 24-hour period when the participants wore both the Holter monitor and the Zio Patch the Holter monitor detected significantly more arrhythmia events than the Zio Patch. However, when device data were compared over the total wear time, the Zio Patch detected significantly more events than the Holter monitor in this patient population.

Gladstone et al. (2014) mentions in an article on atrial fibrillation in patients with cryptogenic stroke that observational studies have shown that there is improved detection of atrial fibrillation with serial or prolonged ECG monitoring. In his study, Gladstone et al. enrolled patients who were over the age of 55, did not have a diagnosis of atrial fibrillation, and had an ischemic stroke or TIA of undetermined cause within the previous 6 months. Patients were randomly assigned in a 1:1 ratio to undergo ambulatory monitoring using a 30-day event-triggered loop recorder (intervention) or a 24-hour Holter monitor (control). A total of 572 patients were randomized to either the event-triggered loop recorder or the Holter monitor. The 30-day ECG monitor was superior to 24-hour Holter monitor for the detection of at least one episode of atrial fibrillation lasting 30 seconds

or longer. Atrial fibrillation was detected in 45 of 280 patients in the intervention group, as compared with 9 of 277 in the control group. Atrial fibrillation was detected clinically, rather than by the study monitors, in only 0.5% of patients within 90 days after randomization. Prolonged monitoring was also superior for the detection of continuous atrial fibrillation lasting at least 2.5 minutes: in 28 of 284 patients in the intervention group versus 7 of 277 in the control group. Prolonged monitoring nearly doubled the proportion of patients who subsequently received anticoagulant therapy for secondary prevention of stroke. This finding was interpreted as a clinically meaningful change in treatment that has the potential to avert recurrent strokes.

Doliwa et al. (2012) compared an intermittent recording device with continuous ECG recordings. Patients used the continuous monitor for one 24-hour period during the 30-day study and used the intermittent recorder twice per day for 30 days and when symptoms were experienced. Significantly more episodes of atrial fibrillation were recorded using the intermittent recorder (82%) compared to the continuous recorder (32%). Doliwa et al. concluded that short-term intermittent recordings over extended time periods are a more sensitive tool compared with short continuous ECG recordings in the detection of atrial fibrillation.

There is some evidence in literature of improved definitive diagnosis, but evidence is lacking in how MCOT use leads to better patient management or treatment. Further studies are needed comparing MCOT with other loop monitors to better determine if MCOT improves health outcomes due to changes in treatment.

Tsang and Mohan (2014) compared the benefits of monitoring patients with MCT with monitoring patients with Event or Holter monitors. A retrospective analysis of over 200,000 patients, of whom 14,000 used MCT only, 54,000 an Event monitor only, and 163,000 a Holter monitor only. The findings showed that the diagnostic yield of patients monitored with MCT (61%) was a significantly higher than that of patients who used the Event (23%) or Holter monitor (24%). Additionally, patients' naive to antiarrhythmic drugs initiate therapy after monitoring at the following rates: 61% for patients who use MCT, 39% for patients who use the Event monitor, and 43% for patients who use the Holter monitor. Significant cost savings for patients who undergo ablation, CABG, valve septa, and heart/pericardium procedures were also identified. The analysis resulted in the conclusion that given the superior outcome of MCT regarding both patient care and hospital savings, hospitals gain by enforcing protocols that favor MCT over Event or Holter monitors.

Miller et al. (2013) performed a retrospective analysis on 156 records of patients evaluated by MCOT monitoring within 6 months of a cryptogenic stroke or TIA. A multivariate analysis was performed to determine predictive risk factors for detection of occult paroxysmal atrial fibrillation (PAF). Miller et al. found that MCOT frequently detected PAF in patients with cryptogenic stroke and TIA and the length of monitoring is strongly associated with detection of PAF, with an optimal monitoring period of at least 21 days.

A small pilot study by Kamel et al. (2013) assessed results of using MCOT to detect previously undiagnosed atrial fibrillation in patients with recent stroke. 40 patients with cryptogenic ischemic stroke or high-risk transient ischemic attack either used the MCOT device or received routine follow-up. Patients and physicians were contacted at 3 months and 1 year to determine any diagnosis of AF. Results found patients with the MCOT device wore it for 64% of the assigned days and 25% were not compliant at all. No patients in the study were diagnosed with atrial fibrillation. Kamel et al. noted the rate of AF detection was lower than expected and device compliance was suboptimal.

Bruniotti et al. (2012) discussed results of a study where MCOT was used with success to diagnose atrial fibrillation in elderly patients when there is atypical presentation of symptoms.

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## Guidelines:

Hayes, Inc provided a synopsis of the clinical evidence for the use of MCOT for home monitoring of cardiac patients in their Health Technology Brief. The synopsis states: [t]he literature search identified a randomized controlled trial (RCT) and four uncontrolled studies that evaluated the CardioNet ECG Monitor for MCOT. Results of these studies suggest that MCOT provides more effective detection of infrequent cardiac arrhythmias than external loop monitors. Specifically, a large multicenter RCT found that clinically significant arrhythmias were detected in 41% of patients with MCOT versus 14% of patients with external loop monitors; this difference was statistically significant. The loop monitors were patient activated for 82% of patients and autotriggered for 18% of patients. MCOT using the CardioNet system was compared with autotriggered cardiac event monitoring in the latter subgroup of patients. Although a statistically significant improvement in definitive diagnoses was obtained with MCOT versus autotriggered monitoring, the RCT did not report whether the autotriggered monitors used had the same ECG data collection capacity as the CardioNet monitor. Information provided by MCOT has been used to guide patient management; however, only two uncontrolled studies reported the changes in the treatments given to patients based on the information obtained from MCOT. Moreover, none of the available studies involved repeated patient examinations over time to determine whether patient health improved as a result of changes in treatment based on information from MCOT. The overall quality of the evidence is low. Additional studies are needed to compare MCOT with autotriggered loop monitors and to determine whether diagnostic information obtained with MCOT improves health outcomes as a result of appropriate changes in treatments.

Ambulatory cardiac monitoring performed with a marketed, FDA-approved device, is eligible for coverage if it can be categorized according to the framework below. Unless there is a specific NCD for that device or service, determination as to whether a device or service that fits into the framework is reasonable and necessary is according to local contractor discretion.

In the 2014 clinical guidelines published by The National Institute for Health and Care Excellence (NICE), the institute recommended an electrocardiogram (ECG) for all individuals, whether symptomatic or not, in whom atrial fibrillation is suspected due to irregular pulse detection. Symptoms of underlying atrial fibrillation include syncope, breathlessness, palpitations, dizziness, chest discomfort or stroke/ transient ischemic attack.

The 2019 American Heart Association, American College of Cardiology and Heart Rhythm Society Guidelines recommend electrocardiographic documentation to establish the diagnosis of atrial fibrillation (AF). It is believed that diagnosis of AF is based on clinical history and physical examination that is confirmed by electrocardiograms (ECG), ambulatory rhythm monitoring (e.g. Holter monitors, event recorders and telemetry) implantable loop recorders, pacemakers or defibrillators.

## Coding:

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

CPT Codes	Description
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

<b>93225</b>	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
<b>93226</b>	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
<b>93227</b>	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
<b>93228</b>	Wearable 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; physician review and interpretation with report
<b>93229</b>	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
<b>93241</b>	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
<b>93242</b>	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
<b>93243</b>	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
<b>93244</b>	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation
<b>93245</b>	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
<b>93246</b>	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
<b>93247</b>	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
<b>93248</b>	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
<b>93268</b>	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
<b>93270</b>	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)
<b>93271</b>	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
<b>93272</b>	External patient and, when performed, auto activated electrocardiographic rhythm derived

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	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
<b>93285</b>	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; implantable loop recorder system
<b>93290</b>	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
<b>93291</b>	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 loop recorder system, including heart rhythm derived data analysis
<b>93292</b>	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; wearable defibrillator system
<b>93294</b>	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, or leadless pacemaker system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
<b>93295</b>	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
<b>93296</b>	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
<b>93297</b>	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
<b>93298</b>	Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional

<b>HCPCS Code</b>	<b>Description</b>
<b>C1764</b>	Event recorder, cardiac (implantable)
<b>G2066</b>	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

### **Billing Guidelines:**

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the

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HPHC Medical Policy

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participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

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**Summary of Changes:**

<b>Date</b>	<b>Changes</b>
<b>1/21</b>	Coding updated
<b>11/20</b>	Coding updated
<b>12/19</b>	Coding updated
<b>7/19</b>	Annual Review; coding and criteria updated
<b>5/17</b>	Criteria revised and coding added. Background, references and supporting information updated.

**Approved by Medical Policy Committee: 1/7/2021**

**Approved by Clinical Policy Operational Committee: 5/14; 12/15; 5/17; 7/19; 12/19; 11/20; 1/21**

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