Molina Clinical Policy
Mobile Cardiac Outpatient Telemetry
Policy No. 428

Last Approval: 12/14/2022
Next Review Due By: December 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

There are several ambulatory cardiac rhythm monitoring devices on the market. This policy is only applicable to mobile cardiac outpatient telemetry.

Mobile Cardiac Outpatient Telemetry (MCOT) consists of an external loop recorder with portable receiver in which the ECG trace is transmitted to remote operating center for real-time monitoring (Dynamed, 2022). MCOT is defined by the American College of Cardiology/American Heart Association/Heart Rhythm Society as a device that records and transmits data (for up to 30 days) from preprogrammed arrhythmias or patient activation to a communication hub at the patient's home. When significant arrhythmias are detected, the monitor automatically transmits the patient's ECG data via a wireless network to the central monitoring station, which is attended by trained technicians 24 hours per day. This offers the potential for real-time, immediate feedback to a healthcare provider for evaluation (ACC, AHA & HRS, 2017).

Regulatory Status

The U.S. Food and Drug Administration (FDA) has cleared several MCOT devices. The following list is not exhaustive, and the current status of the requested MCOT should be verified on the FDA website (product codes: DSI, DXH):

- CardioNet MCOT™ System (CardioNet)
- HEARTLink II™ System (Cardiac Telecom Corp.)
- Heartrak Smart External Cardiac Ambulatory Telemetry System (Mednet Healthcare Technologies, Inc.)
- LifeStar™ Ambulatory Cardiac Telemetry (ACT) System (LifeWatch Inc.)
- SEEQ Mobile Cardiac Telemetry (Medtronic)
- TruVue® Wireless Ambulatory Monitoring Systems (BioMedical Systems)
- Trove® (Biomedical Systems)
- VST™ Vital Signs Transmitter (Biowatch Medical)

Specific brand names are used for illustrative purposes only and is not intended to be a recommendation of one product over another, nor a comprehensive list of all accessible products.

RELATED POLICIES

This policy does not apply to requests for services as part of a surveillance protocol for members engaging in a clinical trial. Refer to *Clinical Trials and Rare Disease: Policy No. 183.*

COVERAGE POLICY

Mobile cardiac outpatient telemetry (MCOT) may be considered medically necessary when **ALL** of the following criteria:

A. Prescribed by a qualified physician with clinical experience and training in cardiac telemetry for **ONE** of the following indications:

1. Member requires monitoring for known non-life-threatening arrhythmias such as paroxysmal atrial fibrillation, other paroxysmal supraventricular arrhythmias, brady-arrhythmias, or intermittent bundle branch block with no prior cardiac telemetry done within the last 3 months. **(AUC Score 7)**

2. Member is recovering from cardiac surgery and has documented atrial arrhythmias with no prior *outpatient* cardiac telemetry done since cardiac surgery. **(AUC Score 7)**

3. Member presents with recurrent severe symptoms (i.e., recurrent syncope or presyncope) with no prior cardiac telemetry done within the last 3 months. **(AUC Score 7)**

AND

B. Submission is accompanied by clinical documentation supporting the medical necessity of the telemetry, including **ALL** of the following:

1. Progress note(s) from a cardiologist or electrophysiologist that prompted the request for a MCOT; **AND**

2. Recent EKG (within 10 days), if available; **AND**

3. Most recent Holter or event monitor or device interrogation report, if available.

LIMITATIONS AND EXCLUSIONS

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. Any indications or criteria listed above have not been met.

2. Inpatient monitoring required or in cases where a hospital setting may be more suitable:
   a. Potentially life-threatening arrhythmias
   b. Patients deemed by the attending physician to require hospitalization
   c. High-risk of developing sustained ventricular tachycardia or ventricular fibrillation

3. Concurrent or prior use of other cardiac surveillance services or cardiac telemetry (e.g., ECG, Holter monitor, or other event recorder) has provided clinical data or information, and MCT is not expected to provide the data/information required for the diagnosis and/or treatment of the patient's condition/symptoms.

4. Prescribed primarily for the daily transmission of ECG rhythm strips or telemetry recordings in the absence of symptoms requiring diagnosis/treatment.

Coverage Limitations

Real-time cardiac telemetry is a service that lasts **up to 30 days** and is used to diagnose or suspected and/or paroxysmal dysrhythmia. Generally, continuing testing for more than 30 days is not medically necessary. In most cases, failure to detect a dysrhythmia after a 30-day monitoring period does not necessitate further testing.

EXCEPTION: Monitoring for longer than 30 days is only medically necessary in exceptional circumstances and must be justified by the treating physician/provider with supporting documentation for review.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Two studies published in 2007 assessed the efficacy of MCOT monitoring for patients with suspected arrhythmia-related symptoms.

Olson et al. (2017) conducted a retrospective chart review to evaluate the diagnostic value of MCOT in patients with palpitations, presyncope, and syncope, as well as its capacity to aid in drug titration. The authors reviewed the clinical records of 122 patients evaluated with MCOT for palpitations, presyncope/syncope, or to monitor the efficacy of a specific antiarrhythmic medication. MCOT identified symptom-related arrhythmias in 96 individuals, including 14 who had had non-diagnostic evaluations earlier. For 21 individuals receiving titration of medications for ventricular rate control in atrial fibrillation and 8 patients following radiofrequency ablation for atrial fibrillation, MCOT provided useful information.

Rothman et al. (2007) conducted a multicenter RCT that compared MCOT to the standard patient-activated external loop event monitoring (LOOP) to monitor patients who had palpitations, presyncope, syncope or a combination of these symptoms. All participants had a high clinical suspicion of malignant arrhythmia, symptoms of syncope, pre-syncope or severe palpitations occurring less frequently than once every 24 hours, and a nondiagnostic 24-hour Holter or telemetry monitor within 48 days prior to enrollment. All 266 participants (n=266) were randomly assigned to either MCOT or an external loop monitor for 30 days. The primary endpoint was either the confirmation or exclusion of an arrhythmic cause for the patient's symptoms. Arrhythmias were classified as either clinically significant or clinically insignificant. A diagnosis was made in 88% of the MCOT group and 75% of the loop event monitoring group. There was no significant difference between MCOT and LOOP in their ability to detect or exclude a cardiac arrhythmia occurring simultaneously with the symptoms (arrhythmia occurred simultaneously with symptoms in 40% and 47% in the two groups respectively in all patients with arrhythmia, and 42% and 40% respectively for patients with syncope/presyncope. The authors also noted that the MCOT system (CardioNet, USA) was compared to patient-activated external event recorders with looping and the study did not compare MCOT to implanted loop recorders, nor was it designed to compare it to auto-trigger loop recorders, which were used in only 16% of the LOOP group's patients. The authors concluded that outpatient telemetry system may detect more arrhythmias than external loop recorders in patients with syncope or presyncope.

Systematic Review and Meta-Analysis

Sposato et al. (2015) conducted a systematic review and meta-analysis of 50 studies (n = 11,658) to estimate the proportion of individuals with newly diagnosed AF following transient ischemic attack (TIA) or stroke. The studies noted diagnostic methods including ECG, continuous inpatient ECG monitoring, Holter monitoring, continuous inpatient cardiac telemetry, outpatient MCOT, external loop recording and implantable loop recorders. Phase 1 was assessment in the emergency room with ECG. Phase 2 (inpatient stay) comprised serial ECG, continuous ECG, inpatient cardiac telemetry and inpatient Holter monitoring. In phase 3, the first ambulatory period, Holter monitoring was utilized. The fourth phase was the second ambulatory period, which consisted of MCOT, external loop and implantable loop recording. Phase 4 revealed AF in 16.9% of patients. The overall AF detection yield after all phases of sequential cardiac monitoring was 23.7% (95% CI, 17.2% to 31.0%). In phase 4, there were no differences between the proportion of patients diagnosed with post-stroke AF by MCOT (15.3%), ELR (16.2%), or ILR (16.9%). In addition, only around 40% of patients persisted into phase 4 for further surveillance after phase 3. Age and risk variables for post-stroke AF differed throughout the 50 studies. This analysis suggests that extended outpatient MCOT detects post-stroke AF, however the proportion of patients diagnosed in phase 4 by implanted loop recording did not differ significantly from those diagnosed by mobile cardiac outpatient telemetry or external loop recording.

National and Specialty Organizations

The **American Heart Association (AHA) / American Stroke Association (ASA)** *2021 AHA/ASA Guidelines for Prevention of Stroke in Patients with Ischemic Stroke or TIA* recommend the following for detection of occult AF (Kleindorfer et al., 2021):

> In patients with cryptogenic stroke who do not have a contraindication to anticoagulation, long-term rhythm monitoring with mobile cardiac outpatient telemetry, implantable loop recorder, or other approach is reasonable to detect intermittent AF (Class 2a, Level of Evidence B-R).

The **American College of Cardiology (ACC) / American Heart Association (AHA) / Heart Rhythm Society (HRS)** guidelines on the evaluation and management of patients with syncope address several ambulatory ECG monitoring options (Shen et al., 2017). The guidelines recommend that the duration and type of monitoring system be determined by the frequency and nature of syncope events. The following external cardiac monitoring approaches can be useful in evaluating selected ambulatory patients with syncope of suspected arrhythmic etiology:

- Holter monitor
- Transtelephonic monitor
- External loop recorder
- Patch recorder
- Mobile cardiac outpatient telemetry

Class IIa, Level B-NR (Class IIa: It is reasonable to perform procedure. Level of Evidence B-NR: Based on moderate-quality evidence from one or more well-designed, well-executed nonrandomized, observational or registry studies).

SUPPLEMENTAL INFORMATION

N/A

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
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 **Note: CPT codes (93228 and 93229) can only be reported once per 30 days of service.
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 **Note: CPT codes (93228 and 93229) can only be reported once per 30 days of service.

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022 New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (Search: cardiac telemetry, cardiac event monitoring). Available from CMS. No NCD identified. Local Coverage Determination (LCD) identified:
   a. L34997: Real-Time, Outpatient Cardiac Telemetry
   b. L33380. Long-Term Wearable Electrocardiographic Monitoring (WEM)
2. Food and Drug Administration (FDA).
   a. FDA approval of CardioNet Ambulatory ECG Monitor with Arrhythmia Detection
   b. FDA approval of HeartLink II (Arrhythmia Detector and Alarm System)

Peer Reviewed Publications

1. Joshi AK, Kowey PR, Prystowsky EN, et al. First experience with a Mobile Cardiac Outpatient Telemetry (MCOT) system for the diagnosis and management of cardiac arrhythmia. Am J Cardiol. Apr 1 2005; 95(7):878-881. PMID 15781022.
2. Olson JA, Fouts AM, Padanilam BJ, Prystowsky EN. Utility of mobile cardiac outpatient telemetry for the diagnosis of palpitations, presyncope, syncope, and the assessment of therapy efficacy. J Cardiovasc Electrophysiol. 2007 May;18(5):473-7. doi: 10.1111/j.1540-8167.2007.00779.x. Epub 2007 Mar 6. PMID: 17343724.
3. Prystowsky EN. Assessment of rhythm and rate control in patients with atrial fibrillation. Journal of Cardiovascular Electrophysiology, 2006; 17(9) (supp). https://doi.org/10.1111/j.1540-8167.2006.00584.x
4. Rothman, SA., Laughlin, JC., Seltzer, J., et al. The diagnosis of cardiac arrhythmias: a prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. J Cardiovasc Electrophysiol. 2007 Mar;18(3):241-7. doi: 10.1111/j.1540-8167.2006.00729.x. PMID: 17318994.
5. Sposato LA, Cipriano LE, Saposnik G, et al. Diagnosis of atrial fibrillation after stroke and transient ischaemic attack: A systematic review and meta-analysis. Lancet Neurol. Apr 2015; 14(4): 377-87. PMID 25748102

National and Specialty Organizations

1. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 guideline for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline from the American Heart Association/American Stroke Association. Stroke. 2021 Jul;52(7):e364-e467. doi: 10.1161/STR.0000000000000375. Epub 2021 May 24. Erratum in: Stroke. 2021 Jul;52(7):e483-e484. PMID: 34024117.
2. January CT, Wann LS, Alpert JS, et al. ACC/AHA Task Force Members. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. Circulation. 2014 Dec 2;130(23):2071-2104. doi: 10.1161/CIR.0000000000000040. Epub 2014 Mar 28. Erratum in: Circulation. 2014 Dec 2;130(23):e270-1. PMID: 24682348.
3. Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2017 Aug 1;70(5):e39-e110. PMID: 28286222.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Tayal AH, Tian M, Kelly KM, et al. Atrial fibrillation detected by mobile cardiac outpatient telemetry in cryptogenic TIA or stroke. Neurology. Nov 18 2008; 71(21):1696-1701. PMID 18815386.
2. Tsang JP, Mohan S. Benefits of monitoring patients with mobile cardiac telemetry (MCOT) compared with the Event or Holter monitors. Med Devices (Auckl). 2013 Dec 9;7:1-5. doi: 10.2147/MDER.S54038. PMID: 24353449; PMCID: PMC3862588.
3. DynaMed. Ambulatory Cardiac Telemetry Monitoring. EBSCO Information Services. Available from Dynamed. Accessed November 22, 2022. Registration and login required.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Medicare National Coverage In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.