External Wearable Devices - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 3.0
Effective Date: December 29, 2023

Important Notices

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Other Notices:

Guideline Information:

Disease Area: Cardiovascular Disease
Guideline Name: External Wearable Devices (Single Service)
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

Literature review current through: December 29, 2023
Document last updated: December 29, 2023

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Service: External Wearable Devices

General Guidelines

- **Units, Frequency, & Duration:** When medical necessity is met based on described clinical criteria, and exclusionary criteria are absent, non-invasive external cardiac monitoring may be conducted using external wearable devices for 24 hours to 30 days, depending on symptom frequency.
- **Criteria for Subsequent Requests:** Subsequent requests may be considered for incomplete or uninterpretable heart rhythm surveillance during the initial recording.
- **Recommended Clinical Approach:** With evidence of symptoms (palpitations, syncope, presyncope, transient dizziness, lightheadedness, or heart failure symptoms)[1] based on clinical history, physical exam, and 12-lead ECG, the most appropriate external wearable monitor should be selected based on patient symptom frequency and suspected duration of the episodes. Daily symptoms may be addressable with a 24-48 hour Holter monitor. Less frequent or asymptomatic events are more likely to be captured with more extended monitoring, either a 30-day loop recorder/event monitor, extended-wear continuous ECG patch device, or mobile cardiac telemetry (MCT). Consideration of the patient's ability to trigger a device effectively may also guide device selection in favor of those with more passive event recording capability.[2,3] If the patient has had 3 or more external wearable devices in the last six months, consider an internal loop recorder. The Mobile Cardiac Telemetry has to have real-time transmission capability. It has to have wireless/cellular communications capability to transmit heart rhythms in real time to a central monitoring station.
- **Exclusions:** Two types of monitors cannot be ordered simultaneously.

Medical Necessity Criteria

Indications

- ➔ **External wearable devices** are considered appropriate if **ANY** of the following is **TRUE**[2-4]:
  - ◆ A Holter monitor is considered appropriate if the patient has experienced symptoms at least once per 48 hours, including **ANY** of the following:
    - Palpitations; **OR**
    - Syncope; **OR**
    - Presyncope; **OR**
    - Transient dizziness; **OR**
    - Transient lightheadedness; **OR**
    - Heart failure symptoms; **OR**
    - Confusional state thought to be related to cerebral hypoperfusion; **OR**
  - ◆ A 30-day event monitor or an extended-wear continuous ECG patch monitor is considered appropriate if the patient has experienced symptoms at least once per 21 days, including **ANY** of the following:
    - Palpitations; **OR**
    - Syncope; **OR**
    - Presyncope; **OR**
    - Transient dizziness; **OR**
    - Transient lightheadedness; **OR**
    - Heart failure symptoms; **OR**
    - Confusional state thought to be related to cerebral hypoperfusion; **OR**
  - ◆ Mobile Cardiac Telemetry (MCT) is considered appropriate if **ALL** of the following are **TRUE**:
    - The patient wore an event monitor or extended-wear continuous ECG patch monitor for at least 14 days without any diagnostic findings; **AND**
    - **ANY** of the following is **TRUE**:
      - Recurrent, unexplained syncope; **OR**
      - Suspected atrial fibrillation (AF) in a patient with cryptogenic stroke, where anticoagulation will be implemented if diagnosed; **OR**
      - Suspected ventricular arrhythmias that would require immediate intervention.

Non-Indications

- ➔ **External wearable devices** are not considered appropriate if **ANY** of the following is **TRUE**[5-6]:
  - ◆ Symptoms suggestive of angina or clinically significant coronary artery obstruction and monitoring would delay other needed testing or intervention[5]; **OR**
  - ◆ The patient has an implantable cardiac device capable of acquiring clinical data of a similar or equivalent quality to an external cardiac monitor; **OR**
  - ◆ The patient requires acute treatment for an arrhythmia; **OR**
  - ◆ Mobile cardiac telemetry (MCT) is not considered appropriate if MCT has already been used once in the last 6 months.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
Holter Monitoring	
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 healthcare professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified healthcare professional
Extended-Wear Patch Monitor/Long-term continuous cardiac rhythm	

monitors	
93241	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
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation
93245	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
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
Event Monitors	
93268	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

	healthcare professional
93270	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)
93271	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
93272	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; review and interpretation by a physician or other qualified healthcare professional
Mobile Cardiac Telemetry (MCT)	
93228	Other qualified health care professional review and interpretation with report of external mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis, and greater than 24 hours of accessible electrocardiogram (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
93229	Technical support for connection and patient instructions for use, attended surveillance for up to 30 days, analysis and other qualified health care professional prescribed transmission of daily and emergent data reports of external mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis, and greater than 24 hours of accessible electrocardiogram (ECG) data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center

Medical Evidence

Ko et al. (2022) conducted a meta-analysis of randomized clinical trials (RCTs) evaluating the use of implantable loop recorders (ILR) for detecting subclinical atrial fibrillation (AF) after cryptogenic stroke. The search included Medline, Embase, Web of Science, and Cochrane Library databases. Three trials involving a total of 1233 participants, were included. The primary outcomes assessed over 12 months included cumulative AF detection and recurrent stroke (both ischemic and hemorrhagic) or transient ischemic attack. The 12-month AF detection rate was significantly higher in the ILR group (13%) compared to controls (2.4%). The use of ILRs was found to be more effective in detecting AF than usual care. The incidence of stroke or transient ischemic attack was 7% with ILR and 9% with regular care. The initiation of oral anticoagulation (OAC) was assessed as a secondary outcome. In patients with detected AF, OAC initiation rates varied across subgroups, with higher rates in cryptogenic stroke and post-embolic rhythm detection compared to stroke of known cause and underlying AF. Overall, the findings suggest that while ILR effectively detects AF, the clinical impact on reducing recurrent strokes may be limited, and careful consideration of patient selection is crucial. Further research is recommended to understand better which patients most likely benefit from ILR implantation.[7]

Buck et al. (2021) report on the PER DIEM RCT, which compared the efficacy of 12 months of ILR monitoring to 30 days of conventional external loop recorder monitoring in detecting AF or atrial flutter in patients with a recent ischemic stroke. A total of 300 patients were included who had an ischemic stroke within 6 months and without known. Participants were randomly assigned to implantable loop recorder monitoring (n = 150) or external loop recorder monitoring (n = 150), with follow-up visits at 30 days, 6 months, and 12 months. Implantable electrocardiographic monitoring for 12 months, compared to prolonged external monitoring for 30 days, detected a significantly greater proportion of patients with AF over 12 months among those with ischemic stroke and no prior evidence of AF. Further research is needed to assess clinical outcomes and cost-effectiveness associated with these monitoring strategies.[8]

National and Professional Organizations

The American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) published a guideline on the *Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay*. The guideline cites support for the use of external wearable

devices for temporary pacing scenarios - for example, for short-term cardiac pacing support during surgery or in the acute setting of a cardiac event.[1]

The International Society for Holter and Noninvasive Electrocardiology (ISHNE) and Heart Rhythm Society (HRS) published a consensus statement on *Ambulatory ECG and External Cardiac Monitoring/Telemetry*.[3]

References

1. Kusumoto FM, Schoenfeld MH, Barrett CN, et al. 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: 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*. 2019 Aug 20;74(7):e51-e156. doi: 10.1016/j.jacc.2018.10.044. PMID: 30412709.
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Clinical Guideline Revision History/Information

Original Date: November 29, 2022	
Review History	
Version 2	9/26/2023
Version 3	12/29/2023