Medicare Medical Policy

External Ambulatory Electrocardiography

Effective Date: 1/1/2025

MEDICARE MEDICAL POLICY NUMBER: 157

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PRODUCT AND BENEFIT APPLICATION



MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Note: Implantable memory loop recorders are addressed in a separate Medicare medical policy (See Policy Cross References below).

Service	Medicare Guidelines
Holter Monitors (CPT codes 93224-93227)	National Coverage Determination (NCD) for Electrocardiographic Services (20.15)
Cardiac Event Monitors (aka external memory loop recorder or ELR) (CPT codes 93268, 93270-93272)	

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria... when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." (§ 422.101(b)(6) – see <u>Policy Guidelines</u> below)

- Medicare Coverage Manuals: Medicare does not have criteria for cardiac patch recorders or mobile cardiac outpatient telemetry (MCOT) in a coverage manual.
- National Coverage Determination (NCD): Some types of ECGs are addressed by the NCD noted above; however, the NCD does not provide guidance for all types of ECGs. The NCD for Electrocardiographic Services (20.15) states, "Certain uses other than those specified above may be covered if, in the judgment of the local Medicare Administrative Contractor (MAC), such use is medically necessary." This NCD is considered "not fully established" under CFR § 422.101(6)(i)(B) as it provides explicit flexibility for coverage decisions beyond the NCD.
- Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA): As of the
 most recent policy review, four Medicare Administrative Contractors (MACs) have LCDs for
 cardiac patch recorders or MCOT (outpatient cardiac telemetry); however, these MACs do not
 have jurisdiction over the plan service area. While Noridian has an LCD for *Electrocardiograms*(L37283), this LCD does not address all types of ECG services that are within the scope of this
 medical policy.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are

considered "not fully established" as defined under CFR § 422.101(6)(i)(B) as the available Medicare coverage policies provide flexibility for coverage decisions beyond the NCD and LCD.

• **NOTE:** The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].

Cardiac Patch Recorder (CPT 93241-93248, 0937T-0940T) Company medical policy for <u>Cardiac: External Ambulatory</u> <u>Electrocardiography</u>

Mobile Cardiac Outpatient Telemetry (MCOT) (CPT 93228, 93229) I. These services may be considered **medically necessary** when Company medical policy criteria are met.

QTc Interval Derived by Augmentative Algorithmic Analysis Using Input from Patient Activated ECG device (0902T) II. These services are considered not medically necessary for Medicare Plan members when Company medical policy criteria are not met. See Policy Guidelines below

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)

POLICY CROSS REFERENCES

Implantable Loop Recorders, MP343

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. (§ 422.101(c)(1))

In addition:

"MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." (§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Four Medicare contractors (MACs) have available LCDs which address patch recorders and outpatient cardiac telemetry or MCOT (CGS, Palmetto GBA, First Coast Service Options and Novitas Solutions). However, these MACs are not the contractor with jurisdiction over the plan service area, and therefore, they are not applicable.

Since there are not fully established coverage criteria for cardiac patch recorders or MCOT available in applicable Medicare statutes, regulations, NCDs or LCDs for the plan's service area, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

The type of ambulatory electrocardiographic monitoring system will determine the CPT code to be used. The following table (Table 1) is a non-exhaustive list of classes and examples of marketed devices relevant to this policy with the proper code

Table 1: Long-term External Ambulatory Electrocardiography Device Classes, Coding and Examples (Non-exhaustive)

Device	System Examples	CPT code(s)
Holter monitors		93224-93227
Cardiac Patch Recorder	 Zio® XT monitor (K202359)35 with myZio app for symptom logging Carnation Ambulatory Monitor (CAM) (K210036) from BardyDx Cardea SOLO from Cardiac Insight, Inc. (K162503) 	93241-93248
External Memory Event Monitors (aka, external memory loop recorder, or ELR)	 M5 Recorder (K202456) from Global Instrumentation, LLC Nuubo System (K173461) BodyGuardian MINI/BodyGuardian MINI Plus (K182030) from Preventice Solutions, Inc. 	93268-93272
Mobile Cardiac Outpatient Telemetry (MCOT)	 Zio AT ECG Monitoring System MCOT Patch, aka Braemar Telemetry Patch System, Model BTPS1000 (K153473) ECG Mini System Continuous ECG Monitor and Arrhythmia Detector (K151269) BodyGuardian Heart (K151188) from Preventice Solutions, Inc. 	93228-93229
Implantable Loop Recorder (not addressed in this policy)	See the separate Medicare medical policy for these devices	33285, C1764, E0616, 0650T

Incorrect coding, which may include billing with codes not specific to the cardiac monitor device class requested, may result in a denial of payment or incorrect reimbursement. It is the provider's responsibility to use appropriate billing practices and use CPT codes which most accurately represent the services provided.

CODES*			
		QTc Interval Derived by Augmentative Algorithmic Analysis	
СРТ	0902T	QTc interval derived by augmentative algorithmic analysis of input from an external, patient-activated mobile ECG device	
	Holter 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	
	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 health care professional	
	Mobile Cardiac Outpatient Telemetry (MCOT)		

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
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
	External Cardiac Patch Recorder
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
0937T	External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; including recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional
0938T	External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; recording (including connection and initial recording)
0939T	External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; scanning analysis with report
0940T	External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional
Event N	Monitor / External Cardiac Loop Recorder (ELR) with Attended Monitoring
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 health care 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 health care professional
Unlisted/Non-Specific Code		
	93799	Unlisted cardiovascular service or procedure
HCPCS	None	

*Coding Notes:

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does not make a procedure medically reasonable or necessary or a covered benefit by Medicare. (Medicare Claims Processing Manual, Chapter 23 Fee Schedule Administration and Coding Requirements, §30 Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is
 submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is
 submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is
 recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website</u> for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling
 edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and
 Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website
 for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
9/2023	Annual review; no criteria changes but language revision due to Company policy change
	from "investigational" to "not medically necessary"
9/2024	Annual review; no change to criteria, update title (removed "Cardiac:")
1/2025	Q1 2025 code updates